                IN THE UNITED STATES DISTRICT COURT
                 FOR THE DISTRICT OF MASSACHUSETTS

IN RE:)
) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE   ) CA No. 06-11337-PBS
WHOLESALE PRICE LITIGATION   ) Pages 1 - 98
)

                    DAUBERT HEARING - DAY ONE

             BEFORE THE HONORABLE PATTI B. SARIS
                UNITED STATES DISTRICT JUDGE

                        United States District Court
                        1 Courthouse Way, Courtroom 19
                        Boston, Massachusetts
                        December 10, 2009, 2:10 p.m.

                    LEE A. MARZILLI
                 OFFICIAL COURT REPORTER
              United States District Court
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1   A P P E A R A N C E S:

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1   I N D E X

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    WITNESS   DIRECT   CROSS   REDIRECT   RECROSS
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4   MARK G. DUGGAN

5   By Mr. Lavine: 25

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    EXHIBITS   PAGE
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8   1-For ID   66

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1   P R O C E E D I N G S

2   THE CLERK: In Re: Pharmaceutical Industry Average

3   Wholesale Price Litigation, Civil Action 01-12257 and 06-11337,

4   will now be heard before this Court. Will counsel please

5   identify themselves for the record.

6   MR. HENDERSON: George Henderson for the United

7   States.

8   MR. LAVINE: Mark Lavine with the U.S. Attorney's

9   office for the Southern District of Florida for the United

10   States.

11   MR. BREEN: Jim Breen for the realtor Ven-A-Care of

12   the Florida Keys.

13   MS. ST. PETER-GRIFFITH: Ann St. Peter-Griffith,

14   United States Attorney's Office, Southern District of Florida,

15   on behalf of the United States.

16   MR. FAUCI: Jeff Fauci, U.S. Attorney's office in

17   Massachusetts.

18   MS. BROOKER: Renee Brooker, U.S. Department of

19   Justice, Civil Division, Commercial Litigation Branch in

20   Washington.

21   THE COURT: That's a mouthful.

22   MR. DALY: Good afternoon, your Honor. James R. Daly

23   on behalf of Abbott Laboratories.

24   MR. TORBORG: David Torborg on behalf of Abbott

25   Laboratories.

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1   THE COURT: All right. So today we're doing a Daubert

2   hearing, is that right?

3   MR. HENDERSON: That's correct, your Honor.

4   MR. DALY: Yes.

5   THE COURT: You all set up a very aggressive agenda

6   for me. We will not be getting to the motions for summary

7   judgment. There was some proposal that we do. I haven't even

8   read them. It took me four days just to read the Daubert and

9   the spoliation papers, without even going into all the

10 appendices. I don't know how you thought I was going to do the

11 summary judgment motions too, but that's just not going to

12 happen. So I'm unprepared, and it can't happen.

13   So as far as I'm concerned, I'm going to take my time

14 trying to understand the statistics. I understand I've got

15 three witnesses anyway, is that right?

16   MR. DALY: Yes, your Honor.

17   THE COURT: And do we have any time limitations,

18 people who have to be on a plane somewhere?

19   MR. DALY: Not really, your Honor, from my

20 perspective.

21   MR. LAVINE: Not until tomorrow night.

22   THE COURT: I've got that time limitation. We will

23 not be here Friday evening. But, in any event, let's get going

24 on the statistics. We're going to start with Professor Duggan,

25 or Dr. Duggan, whatever we're calling him, and he should get up

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1   first. The government should put him on. He should explain

2   the methodology to me. I don't want to start with cross

3   because I don't understand it well enough. This is a tutorial

4   to help me understand it, and then you can cross.

5   Do you have any idea how long it will take you to put

6   him on?

7   MR. HENDERSON: Your Honor, I'll turn it over to

8   Mr. Lavine, who will be handling the Daubert hearing.

9   THE COURT: Mr. Lavine.

10   MR. LAVINE: Judge, it may take -- two hours would get

11   us through in fairly detailed fashion his methodology.

12   THE COURT: Good.

13   MR. DALY: Your Honor, I was thinking that it might

14   benefit the Court if we had some brief opening remarks just to

15   put what it is that we're attacking and not attacking into

16   context, so I had --

17   THE COURT: That's terrific, if you want to, although

18   understand that I did plod my way through the briefs, not the

19   gazillion-page expert report, but I did go through the briefs.

20   So I don't want a really long one, maybe just to highlight it,

21   five or ten minutes a side? Does that make some sense?

22   MR. DALY: Certainly, your Honor.

23   THE COURT: Would you want to do that?

24   MR. LAVINE: Sure, Judge. I can get through in just a

25   few minutes to let you know the key points that we --

1   THE COURT: Well, since it's actually their motion,

2   the question -- well, why don't you go first, and they can go

3   second, of what you're planning on presenting, almost like an

4   opening, and then what you're planning on focusing on, and then

5   we can get into the testimony.

6   MR. LAVINE: Thank you, Judge.

7   There is five key points that we'd like to demonstrate

8   to the Court in connection with this hearing, that, first of

9   all, using nonrandom samples are a tried and true method that

10   are routinely admitted into evidence and used in peer-reviewed

11   publications. We see many references to it. Even in the

12   Reference Manual For Scientific Evidence, they directly discuss

13   the use of nonrandom samples. The key question is the same

14   whether the selection of the sample is random or nonrandom: Is

15   the sample sufficiently representative of the universe to allow

16   for a reliable extrapolation? So we'll show that nonrandom

17   samples are routinely used and admitted into evidence.

18   Number two, that the linchpins of Abbott's motion,

19   this idea that Dr. Duggan, and I quote, "did nothing at all" to

20   evaluate the representativeness of the sample, and that he

21   extrapolated using no data whatsoever, is just completely

22   wrong, a hundred percent directly refuted by the plain facts in

23   the case. Dr. Duggan has considered dozens of different

24   factors to evaluate the suitability of the samples. He's

25   tested his methodology in many different ways, and he only

1   extrapolated in situations where he had reliable, verifiable

2   data rooted in actual paid Medicaid claims.

3   Third is that although we're not here to evaluate

4   whether Dr. Duggan reached the correct solution, the correct

5   answer, because Daubert we're looking at reliability, not the

6   right or wrong, the test that Dr. Duggan has performed, his

7   large sample size, his examination of the data and the

8   suitability and the representativeness, the way he made his

9   different adjustments and the different tests for robustness,

10   have demonstrated that he is right on target, thereby

11   demonstrating that he has used a reliable methodology. In

12   general, his tests have shown an exactitude to within just a

13   few percent of the actual number he's provided in his report.

14   Next, everything that Dr. Duggan has done is

15   transparent. You're able to see everything that he's done in

16   his work papers. And all of his work is replicable, has in

17   fact been replicated by Abbott. And all of his work is

18   testable. Dr. Duggan has done many tests to evaluate the

19   precision of the work that he's done, as compared to Abbott;

20   they have not actually tested it. But it was fully testable.

21   If they had chosen to do so, they could have tested it.

22   And, last, your Honor, Abbott's nonsystematic

23   cherry-picked counterexamples are just extremely weak evidence

24   for the points that they're trying to put forth here. This is

25   a universe covering millions and millions of claims over eleven

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1   years, over fifty different public healthcare programs,

2   forty-four different NDCs. You can find an example of almost

3   anything. To evaluate whether or not the samples were

4   representative, you need to do a systematic review. You need

5   to look at the overall makeup of the sample and the overall

6   makeup of the population, and zeroing in on cherry-picked

7   counterexamples just sheds very little light on that.

8   THE COURT: Let me ask you this. The thought occurred

9   to me as I was wading through this very dense discussion: Why

10 can't the government, if there's a false claim, just go on

11 penalties? Why am I trying to figure this out?

12   MR. LAVINE: Well, we always try to start --

13   THE COURT: In other words, you get $5,000 to $11,000

14 per claim, right?

15   MR. LAVINE: Yes. We have some pretty solid evidence

16 where Abbott -- because Abbott ran their own pharmacies, and we

17 have calculated they submitted enough claims to generate just

18 from their own formula.

19   THE COURT: So you're saying you don't get the -- it's

20 a False Claims Act case, right?

21   MR. LAVINE: Yes.

22   THE COURT: So for every claim there's a penalty,

23 right, a false claim that they caused to be produced, right?

24   MR. LAVINE: Yes. I completely agree.

25   THE COURT: If I'm understanding it. This is so

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1   complex that I was sort of wondering why you didn't just rely

2   on the penalty provision.

3   MR. LAVINE: Well, it just seemed to be a reasonable

4   approach to try to calculate the damages.

5   THE COURT: But does it matter?

6   MR. LAVINE: Dr. Duggan was able to --

7   THE COURT: Excuse me. Does it matter? In other

8   words, is there a dollar difference?

9   MR. LAVINE: Well, sure. Our individual -- our single

10 damage calculations are approximately $106.5 million.

11   THE COURT: So what would it be if it was a penalty?

12   MR. LAVINE: The penalties associated with the claims

13 that tie to that $106 million in damages would be extremely

14 high. I haven't actually calculated that because I know it's

15 billions of dollars, and we have tried to focus a little bit

16 too in the penalty side on -- because Abbott had their own

17 pharmacy and submitted claims directly to Medicare and Medicaid

18 for these drugs, just those claims would be 350 --

19   THE COURT: The second question I didn't understand

20 based on all the papers, and I should have, I'm sure -- I was

21 often reading them at night -- so there are claims of

22 spoliation. Is any of the data that we're talking about here,

23 when he says he only does ten states instead of the remaining

24 states, is that because the data didn't exist, or is it because

25 he just chose to do ten states? If I told him to do every

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1   single state, is the data there?

2   MR. LAVINE: We were able to collect directly from the

3   states data from approximately thirty states.

4   THE COURT: So for thirty states, you could actually

5   do this state by state?

6   MR. LAVINE: Yes, except the effort involved with

7   mastering the nuances of the data sets of each of these

8   individual states, it's quite extensive.

9   THE COURT: I understand, but we are talking about

10   billions of dollars, so I'm just trying to understand.

11   MR. LAVINE: Sure.

12   THE COURT: So I want to understand what you have and

13   you don't have. You have data. Is that the SDUD data?

14   MR. LAVINE: There's three types of data.

15   THE COURT: Yes.

16   MR. LAVINE: We have the data collected directly from

17   the states.

18   THE COURT: And that's called what?

19   MR. LAVINE: The state-produced data.

20   THE COURT: That's just called state-produced data.

21   MR. LAVINE: Right.

22   THE COURT: And you have that for how many states?

23   MR. LAVINE: Approximately thirty.

24   THE COURT: And for most quarters, or does it depend

25   on the state?

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1   MR. LAVINE: It depends on the state.

2   THE COURT: All right. And you have that for thirty?

3   MR. LAVINE: Approximately.

4   THE COURT: Okay. And then --

5   MR. LAVINE: The next level of data is, in the

6 ordinary course of the operation of the Medicaid program, each

7 individual state reported their drug reimbursement information

8 to the Medicare -- I'm sorry -- to CMS.

9   THE COURT: Right.

10   MR. LAVINE: And we have that data that covers all

11 fifty states.

12   THE COURT: And that's what?

13   MR. LAVINE: There's two types of data that do that.

14 One is called SMRF, S-M-R-F, or SMRF/MAX.

15   THE COURT: Like the little blue guys who run around?

16   MR. LAVINE: Right.

17   THE COURT: All right, so SMRF/MAX and --

18   MR. LAVINE: And then the third set is called SDUD,

19 S-D-U-D, the State Drug Utilization Data.

20   THE COURT: And I couldn't figure out what the

21 difference between those two was. It wasn't clearly explained.

22   MR. LAVINE: Well, the SMRF/MAX data is claim-by-claim

23 data. You can see a single prescription, the amount billed and

24 paid.

25   THE COURT: And we have that for all fifty states,

Page 13

1   right?

2   MR. LAVINE: Well, not for every time period, but the

3   combination of the three types of data gives us data for all

4   fifty states. And if Dr. Duggan didn't have at least one of

5   those three sources, he of course did not calculate any

6   damages. He would only calculate damages if --

7   THE COURT: So SDUD is -- so SMRF is for how many

8   states do you have it?

9   MR. LAVINE: The SDUD and the SMRF/MAX both cover all

10   fifty states.

11   THE COURT: And is that all he really needs to

12   calculate?

13   MR. LAVINE: Well, what he did was to focus on the

14   claim-by-claim data from the states to do his most detailed

15   analysis, and then extrapolated using the SMRF/MAX and the SDUD

16   data.

17   THE COURT: All right, that's what he's going to tell

18   me about?

19   MR. LAVINE: Right, right. And that's why we say he

20   had data underlying every penny of the damages because the SDUD

21   and the SMRF/MAX reflect actual Medicaid claims paid by the

22   state.

23   THE COURT: So when Abbott and the others complain

24   about spoliation, that's the first category of state-produced

25   data?

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1   MR. LAVINE: Yes.

2   THE COURT: You have everything else?

3   MR. LAVINE: There are theories along the line because

4 we --

5   THE COURT: No, I understand, but it's the first

6 category of the three, that's what's not there?

7   MR. LAVINE: Yes, right.

8   THE COURT: The second two categories exist?

9   MR. LAVINE: Yes, but, again, and there's charts in

10 the expert report that show --

11   THE COURT: Yes, but the expert is like this, okay?

12   MR. LAVINE: Right, I understand.

13   THE COURT: Okay, so let's --

14   MR. LAVINE: But I want to make sure you understand.

15 The data, the SDUD and the SMRF/MAX, for example, might not

16 cover a certain state for a certain period, or the SMRF data

17 might and the SDUD doesn't. It's the combination of the three

18 databases that was used by Dr. Duggan, where he could use one

19 to check on the other, and only did calculations if he had at

20 least one of those sources.

21   THE COURT: All right. Well, I'll ask him about that.

22 Thank you, thank you.

23   All right, so from Abbott's point of view?

24   MR. DALY: Your Honor, to pick up where you left off,

25 our problem with the data that we're raising is that the claims

1   data, the state-produced data, he only had for ten states.

2   That's the data that brings you down to the transaction level

3   that actually allows you to look at the transaction and

4   determine what the dispensing fee was, how much was paid, how

5   much was charged, whether it was a U and C, whether there was a

6   MAC, et cetera, et cetera, et cetera.

7   Our problem that we raise with respect to Dr. Duggan

8   on the one hand and spoliation on the other is that there's

9   only ten states of it that they used in the expert analysis.

10   There may be as many as twenty or twenty-five -- I don't think

11   it's thirty -- states where the data was available.

12   THE COURT: Where the data --

13   MR. DALY: The claims data, the state-produced claims

14   data was available.

15   THE COURT: For thirty states?

16   MR. DALY: I don't think it was quite thirty. It was

17   more like twenty or twenty-five. But the point is that

18   Dr. Duggan didn't use it. He only used ten. And when you move

19   to the extrapolation, the SDUD data and the SMRF data, that's

20   simply aggregate data, so --

21   THE COURT: But you've had access to the state data,

22   though, right?

23   MR. DALY: We did. In fact, some of the stuff that

24   Dr. Duggan used is stuff that we got pursuant to subpoena.

25   THE COURT: So you both have similar access to the

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1   thirty states of the claim-by-claim?

2   MR. DALY: Yes, and they decided not to prove up their

3   case on a state-by-state basis.

4   THE COURT: But you've had access to it, in other

5   words, to discredit it, is that right?

6   MR. DALY: Well, in certain circumstances, yes, Judge.

7   THE COURT: All right, so you've both had access to

8   the first category, the claim-by-claim, right?

9   MR. DALY: Well, except for that it's gone, Judge.

10   Most of the data from the states --

11   THE COURT: I thought you said you had it --

12   MR. DALY: We've got some.

13   THE COURT: -- for thirty states.

14   MR. DALY: Twenty-five or so. But they have it too.

15   We all have that. We all have that.

16   THE COURT: All right, for thirty states, you all have

17   it. What's missing are twenty states.

18   MR. DALY: Correct.

19   THE COURT: All right, and maybe the District of

20   Columbia, I don't know. So, all right, and then you all have

21   the data with respect to the aggregate that's at CMS, right?

22   MR. DALY: Right.

23   THE COURT: And you say that you need to go into the

24   weeds with respect to the thirty states?

25   MR. DALY: Yes, Judge, and because what Dr. Duggan

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1   does and what the government does is, they take the detailed

2   analysis of the ten states, and then they extrapolate that to

3   the other thirty-eight. And what they use is the SDUD and the

4   SMRF data. The SDUD and the SMRF data is aggregate. So what

5   they do is, they say: Okay, here's my ten states, the only

6   ones I care about, and I'm going to go ahead and look at these

7   states. And instead of doing any state-by-state analysis for

8   the other thirty-eight, I'm going to take my ratio of

9   difference for these states, and I'm going to extrapolate it to

10   the SDUD and SMRF data, which is simply aggregate. It tells

11   you quarter by quarter by NDC that, you know, Oklahoma spent

12   $500,000 on vanco. And so they take this ratio that they

13   calculated based on the ten states, and they apply it to the

14   other without actually looking at the claim data, without

15   looking to see whether there are MACs involved, the U and C

16   charges, without looking at the state's formula, because the

17   SDUD data and the SMRF data don't allow you to do that. And

18   perhaps the best proof of that --

19   THE COURT: Well, you gave me a very good example, but

20   you gave me one or two. So the question is, have your experts

21   looked at it to show that those are -- looked at another state

22   or another five states, since you had it too, to show that --

23   MR. DALY: We have --

24   THE COURT: I mean, it is cherry-picked. Now, maybe

25   it's representative or maybe it's not, but it was hard to tell

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1   from the brief.

2   MR. DALY: We have done a variety of examples that our

3   experts are going to talk to you about.

4   THE COURT: All right, so that's what I'll be hearing,

5   whether or not those cherry-picked examples, which make your

6   point, are idiosyncratic or whether they're representative.

7   MR. DALY: Right, and they're not. And some of the

8   examples come from Dr. Duggan's own work, so we'll be using

9   stuff that he discovered that basically show the point of the

10   extensive variation and variability between states. I mean, he

11   calculates ratios of difference for the same NDC, for the same

12   drug, for the same quarter. In one state it might be a

13   3 percent difference that he charges as damages to us. In

14   another state it might be 90 percent.

15   THE COURT: So can I ask you the other question I

16   started him off with?

17   MR. DALY: Sure.

18   THE COURT: If you win, you know, other than in these

19   10 states, isn't it apparent victory because I don't then just

20   apply a penalty per claim?

21   MR. DALY: Well, there's a battle to be waged on that,

22   as you might expect, your Honor.

23   THE COURT: Which is what?

24   MR. DALY: What the cases say is that --

25   THE COURT: I mean, even if I went down to $5,000, the

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1   lowest range, it's still doing better than the difference.

2   MR. DALY: Well, we don't know that because what the

3   cases say, Judge, in an FCA claim is that the penalties are

4   assessed not on claims, not by claims filed by doctors, but on

5   the defendants' acts. So what the cases have come out, the

6   state cases that we've looked at that your Honor is aware of

7   that have been decided, what the courts have done there is,

8   they don't look at every claim that was submitted by a third

9   party. They look at the defendants' acts, and the defendants'

10   acts are, allegedly, the submission of prices to the compendia;

11   and that may happen once a quarter, or it might happen once a

12   year. So that's why --

13   THE COURT: Oh, I see. So that's the debate --

14   MR. DALY: That's why the government is not --

15   THE COURT: -- whether you get a one $11,000 hit or

16   whether you get it per claim.

17   MR. DALY: Correct.

18   THE COURT: And that's why it's worth it to go through

19   this exercise because there's at least some legal confusion

20   about what I'd look at.

21   MR. DALY: Yes, your Honor.

22   THE COURT: All right.

23   MR. DALY: There will be a dispute on that, but, yes.

24   THE COURT: Okay.

25   MR. DALY: And our problem with what Dr. Duggan does

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1   is probably -- I'm just going to read from two sentences from

2   his affidavit that he files, and what he says is that "As I

3   explain in my rebuttal report, quote, 'What I've done is not a

4   random sample of the entire universe of fifty states. I chose

5   to focus on the larger states to obtain the maximum amount of

6   precision. Put simply, it is more important to the total value

7   of the damages to be as accurate as possible for the state of

8   Florida than it is in the state of Vermont.'"

9   And so what Dr. Duggan is telling you is that he put

10   more rigor into the 10 states because when he chose his sample,

11   which isn't a random sample -- it isn't any kind of sample at

12   all -- he just wanted to look at the big states, and he didn't

13   care very much about Vermont and New Hampshire and Oklahoma.

14   THE COURT: Well, have you done an analysis of Vermont

15   and New Hampshire and Texas?

16   MR. DALY: I don't know that we have the data for

17   that. There's information about Texas, the point being, he

18   himself says, "I don't have the same degree of rigor on those

19   states because I didn't care about them very much," compared to

20   a big state like Florida or a big state like Illinois. And

21   what we're saying is that if they're going to assess damages --

22   it's their burden to prove damages -- if they're going to

23   assess damages against us, the dollar that Abbott has to pay,

24   if it comes to that, for Vermont is just as valuable as the

25   dollar for Florida, and it ought to be having the same rigor.

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1   THE COURT: Take New York and Vermont which are

2   adjacent to each other, I mean, why wouldn't it be reasonable

3   to say, assuming that their regulatory schemes are similar,

4   that you could extrapolate from one to the other?

5   MR. DALY: Well, interesting question, and we'll get

6   into that, but the OIG and Dr. Duggan himself have seen in the

7   work that he's done that the same states with the exact same

8   exact formula -- let's call it AWP minus 10 -- can have wildly

9   different reimbursements by NDC, by quarter. So you have the

10   same state AWP. One state, he calculates a 30 percent

11   DIFF-FRAC, he calls it, or a ratio of difference; and the state

12   with, you know, two over that has AWP minus 10, they're

13   calculating it at 80 or 90. So the fact that a state has the

14   same formula doesn't mean anything, and there are OIG studies

15   which we'll get into very briefly as well which go into this in

16   great detail.

17   THE COURT: All right, but let me ask you, has your

18   expert done a study that shows that it's completely out of

19   whack comparing the average of these ten, if that's what it is,

20   with, let's say, some of the other states?

21   MR. DALY: Yes, your Honor.

22   THE COURT: Okay, I shouldn't have said "out of whack."

23   I guess that's a --

24   MR. DALY: Well, no, I do that all the time.

25   THE COURT: "Out of whack" might have a -- but,

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1   anyway, so you're going to tell me about that.

2   MR. DALY: Yes.

3   THE COURT: All right.

4   MR. DALY: And so just to talk a minute about

5   extrapolation, there's two kinds of extrapolation going on here

6   when we talk about Medicaid; and even for the 10 states that

7   Dr. Duggan has, he does not have data for all the years, even

8   for those states. And so you'll see we'll have charts --

9   THE COURT: Yes, but that's less hard for me. I mean,

10   you know, this question of if you've got ten quarters, can you

11   extrapolate to the next fifteen, that's less hard than across

12   states.

13   MR. DALY: Well, okay, and I think that there are

14   gradations of reliability here. But in that, if you take

15   Michigan, for example, which is one of the 10 states that he

16   uses, he only has five quarters, and those are 2001 and the

17   last quarter of the year 2000. And he extrapolates those five

18   quarters ten years back all the way to 1991, and so you've got

19   basically nine years of the damage period being extrapolated

20   from the very most recent five quarters. And what you end up

21   with -- so there's an example --

22   THE COURT: You know, actually, I really don't want to

23   take up too much more time. I read your briefs. I mean, so

24   the four kinds of extrapolation, are we talking about, is

25   extrapolation across states?

Page 23

1   MR. DALY: Yes.

2   THE COURT: Extrapolation within states, right?

3   MR. DALY: Yes.

4   THE COURT: There's extrapolation across carriers, and

5   there's extrapolation within carriers, right?

6   MR. DALY: Exactly.

7   THE COURT: All right, so those are the four things

8   that you're challenging?

9   MR. DALY: Yes, your Honor.

10   THE COURT: Is there anything else you're challenging?

11   MR. DALY: No, your Honor, and I did want to point out

12   that when you get into Dr. Duggan's numbers -- so we're not

13   challenging a lot here. The states where he has the data

14   before he does the in-state extrapolation, we're not

15   challenging that. There's no Daubert challenge. We have a lot

16   to say about that on the merits at trial, but for Daubert,

17   we're fine with that. We challenge the in-state and then the

18   across-state.

19   The same thing on the carriers. Where he has the four

20   or five carriers where he has the arrays, even when he doesn't

21   have arrays for every J-Code that he's calculated, we're not

22   challenging those. And in each case it ends up being about

23   50 percent of the damages for Medicare and 50 percent of the

24   damages for Medicaid. And I wanted to make that point because

25   we're not challenging everything. We're only challenging that

Page 24

1 which we feel has gone beyond the data, and that's our point

2 here.

3   THE COURT: And you're not challenging his

4 qualifications?

5   MR. DALY: No, your Honor.

6   THE COURT: Okay, good. Let's hear from him.

7   MR. DALY: Thank you.

8   MR. LAVINE: Your Honor, may I take one minute to

9 respond?

10   THE COURT: No. Let's just do it. All right, I'm

11 sure he's a busy man, right? He's taking care of the whole

12 Healthcare Bill, so let's get him out of here, all right,

13 because I'm hoping here, it's 2:35, you're going to take two

14 hours, is that it?

15   MR. LAVINE: Probably.

16   THE COURT: So if you can do an hour and a half, and

17 we're going to need to do a break for the Court Reporter, so we

18 just need to move through this.

19   MARK G. DUGGAN

20 having been first duly sworn, was examined and testified as

21 follows:

22   THE CLERK: Would you please state your name and spell

23 it for the record.

24   THE WITNESS: Dr. Mark Gregory Duggan. It's spelled

25 M-a-r-k G-r-e-g-o-r-y D-u-g-g-a-n.

Page 25

1   DIRECT EXAMINATION BY MR. LAVINE:

2   Q.   Dr. Duggan, just briefly, can you give the Court the

3   benefit of your --

4   THE COURT: I've seen the CV. Let's just get to the

5   merits. He's qualified.

6   MR. LAVINE: All right, thank you.

7   Q.   Dr. Duggan, what is your understanding of why we are here

8   today?

9   A.   It is a Daubert hearing, and that there are certain

10 components of my analysis that Abbott and Abbott counsel are

11 challenging, and I'm here to discuss the reliability, the

12 validity of the methodology that I deploy in my analyses.

13   THE COURT: Let me ask you this: Have you ever

14 testified before?

15   THE WITNESS: I have not.

16   THE COURT: All right, so sit back, relax. All right,

17 so the key is -- do you teach undergraduates at Maryland?

18   THE WITNESS: I do.

19   THE COURT: All right, I'm an undergraduate for this

20 purpose, so when you're starting to talk statistical concepts,

21 I had one undergraduate course in statistics, so if you can

22 break it down and talk to me more than you do the lawyers.

23   THE WITNESS: Okay, and look at you.

24   THE COURT: Yes, you're teaching me what happened

25 here, all right?

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1   THE WITNESS: Okay.

2   Q.   What is your understanding of the key critiques leveled by

3   Abbott at your study, at your analysis?

4   A.   I think that they were just described, outlined by counsel

5   to some extent, the notion being that -- I think the criticism

6   being that the extrapolation methodology that I utilize in my

7   analyses is unreliable and not valid; it's at a high level.

8   Q.   And in particular, what is your understanding with respect

9   to the data?

10   A.   Well, my reading of the various documents that they've

11   submitted and their experts have submitted indicates that they

12   have a sense that I'm extrapolating to periods or products or

13   states and what have you for which I have no data. And in this

14   report, your Honor, you may have seen that I deploy quite a lot

15   of data, and I think that is flat out wrong.

16   Q.   And then in connection with the representativeness of the

17   sample, what is your understanding of the particular point

18   they've leveled there?

19   A.   Well, once again, my reading, sort of aggregating up all

20   of the documents and so forth, is that Abbott and Abbott

21   counsel are claiming that I've done really nothing to gauge the

22   appropriateness of taking results for this very large sample of

23   claims to estimate what the corresponding "difference," as I

24   call it in the report, and I can define that later, would be in

25   this group of claims that are outside of the sample.

Page 27

1   Q.   So do you agree or disagree that you did nothing and

2   extrapolated with no data?

3   A.   I disagree.

4   Q.   And can you characterize the thoroughness of the work that

5   you performed.

6   THE COURT: No. Let's just explain it. What did you

7   do?

8   Q.   Well, what were you asked to do?

9   A.   In my judgment, having done years and years of work on

10   Medicaid/Medicare and similar sorts of government programs,

11   healthcare issues, I did an enormous amount to assess the

12   validity of this methodology, and I can -- I don't know when we

13   want to sort of drill down.

14   THE COURT: Now.

15   THE WITNESS: Okay.

16   THE COURT: So start really with baby steps. What

17   data? What did you do? What was the methodology?

18   THE WITNESS: Okay, great. So two programs at issue

19   that I'm analyzing really in this report, the Medicaid program

20   and the Medicare program. For Medicaid, I utilized three

21   different sets of data, as counsel explained earlier: the

22   state-produced claims data for states like Florida, California,

23   New York and so forth; the CMS claims data for the remaining

24   38 states; and the CMS S-D-U-D data, SDUD data. And just to

25   give you a sense of the sort of level of information that's

Page 28

1   contained in these different files, so the state-produced

2   claims data and the CMS-produced claims data are very similar.

3   There are some discrepancies, there are minor discrepancies,

4   but basically there's a claim per -- for the typical

5   prescription that gets dispensed at a pharmacy, a claim is

6   going to appear in both of those data sets, if I have the data

7   for them.

8   The S-D-U-D data, the State Drug Utilization Data, is

9   aggregate data by state, by NDC, by quarter. And so in

10 thinking about what sort of level of information is here --

11   (Discussion off the record.)

12   THE WITNESS: So 50 states, 44 products, 44 quarters,

13 okay. So that's basically, in terms of how many observations

14 are in this data, it's essentially 50 times 44, times 44, which

15 is approximately 100,000.

16   Now, some of those cells will be empty. Maybe Alaska

17 won't have any utilization for a particular product in a

18 certain quarter, but that's to give you a sense of sort of

19 order of magnitude. So while the term "aggregate data," it is

20 aggregate data, it's still at a very fine level. Because it's

21 100,000 different cells on three million claims, it's --

22   THE COURT: A hundred thousand different --

23   THE WITNESS: Cells. When I say cells, I mean like

24 state NDC quarter combinations. And some of those cells, those

25 combinations will be empty, there won't be any claims. But for

1   many, tens of thousands of them, there are.

2   THE COURT: And is there a difference between the

3   state-produced data and the CMS claims data which you say you

4   have for 38 states?

5   THE WITNESS: There are some differences between the

6   two.

7   THE COURT: Like what?

8   THE WITNESS: So, for example, the units variable that

9   is -- so one of the things, if one's looking, sort of looking

10   at a claim and trying to replicate, how did this methodology

11   arrive at $60 paid, and so the state-produced data does have

12   typically a units field, which can be multiplied by the AWP and

13   then times .9 or .95, depending on the state. So there's a bit

14   more detail in there, a units variable that's included in

15   across the years, things like, typically the dispensing fee is

16   broken out and so forth, so there's a bit more detail in it.

17   But, also, many of the things that are in the claims

18   data are also in the CMS data. So, for example, the paid

19   amount is in both sets of data. The usual and customary, the

20   sort of charged amount, that's in both sets of data. The

21   product is in both sets of data, the state, the quarter. There

22   are many things that are common, but there are a few minor

23   differences.

24   THE COURT: Is the MAC in both, whether there's a MAC

25   used, a maximum allowable cost?

Page 30

1   THE WITNESS: No, but to some extent, the MAC would be

2   embedded in the paid amount, but there isn't necessarily a MAC

3   indicator in the SMRF/MAX.

4   THE COURT: Because that's all that -- that's what you

5   pay? That's why it's in the embedded amount?

6   THE WITNESS: That's exactly right, so if there's a

7   MAC of 30 in effect --

8   THE COURT: Could you tell that? In other words, so

9   if you don't have the state -- the state data will give you

10   whether there's a MAC, right?

11   THE WITNESS: Typically, yes.

12   THE COURT: So if you're looking at the federal data,

13   the CMS data, and you don't know whether there's a MAC or not,

14   can you look back to the regulatory scheme to find out whether

15   in fact they're following a MAC. Would you be able to go --

16   for example, Massachusetts in a given year might say, "This is

17   our MAC"?

18   THE WITNESS: Right, so it is possible to back out

19   this kind of information in certain instances, and to the

20   extent that these -- so it's possible, and certainly a look at

21   the adjudication methodologies used by the states can shed some

22   light on this. But, also, to the extent that a state pays a

23   MAC, let's say, that would be less than what would end up from

24   AWP, for example, that will be reflected in the paid amount,

25   and so that is sort of -- I don't know where -- there's so many

Page 31

1   elements, so I'll just sort of go into this because I think

2   this is useful.

3   One of the things that I did to assess the

4   comparability of those 10 states for which I used

5   state-produced data to the 38 is, I look: For the 44 products

6   that are at issue in this case, are the average amounts paid

7   per claim comparable between the two groups on average? So is

8   it the case that --

9   THE COURT: Between what two groups?

10   THE WITNESS: The 10 and the 38. And here if you -- I

11   don't know if you have the report in front of you.

12   THE COURT: I don't have it right in front of me.

13   THE WITNESS: Yes, no, that's okay. If not, I can

14   just explain. So there's a period of time when I have the CMS

15   claims data for all of the states, for all of the essentially

16   48, 49 states that are being analyzed; and I can see, is it the

17   case that systematically there's a systematic pattern? Is

18   there a difference in the sense that the 10 states tend to

19   reimburse more per claim than the 38?

20   So it would be -- suppose it were true that I found

21   that on average, the 10 states paid $50 per claim for one of

22   the vanco NDCs, but the remaining 38 states were paying $10 per

23   claim. That would potentially be driven by, those 38 states

24   for whatever reason have much more aggressive MAC programs in

25   effect across the board, right? So this is exactly an example

Page 32

1   of the kind of thing that I did to assess the comparability of

2   the two states. It turns out that more often than not -- and

3   this is true even when I pull Ohio from the analysis, which we

4   can talk about -- the average amount paid in the 10 is -- I

5   have to go back to my footnote --

6   MR. LAVINE: Your Honor, I have copies of the report.

7   THE WITNESS: I'm looking at Footnote 45.

8   THE COURT: I am sure I didn't read the footnote.

9   THE WITNESS: Yeah, right, so it's the average

10   reimbursement -- I just don't want to flip it.

11   THE COURT: Well, Which footnote are we talking about?

12   THE WITNESS: It's Footnote 45 on Page 78.

13   MR. LAVINE: Your Honor, No. 1 would be the beginning

14   of the exhibits to the initial report, Tab No. 1.

15   THE COURT: Yes, well, I've got 45.

16   THE WITNESS: Yes, it's in Tab B, I think?

17   THE COURT: Yes, I've got it.

18   THE WITNESS: So it's around Page 78. And so you see

19   there in that footnote I'm describing how basically I'm

20   looking, on a per-claim basis, how does reimbursement, looking

21   for each of the 44 products, differ for those 10, the Floridas

22   and so forth, versus the remaining 38, the Vermonts? And if

23   anything, it appears from this comparison that average

24   reimbursement per claim, it's more often than not it is higher

25   in the remaining 38.

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1   So if I thought, well, you know, those 38, it's just

2   going to be true that they have much more aggressive MAC

3   programs in effect, I would have expected the opposite in a big

4   way. But, you know, it's basically half the time: 24 more

5   often than not, 24 out of 44 cases, and 23 out of 44 when we

6   drop Ohio; the average amount paid is higher in the 38 than in

7   the 10, suggesting it's not true. And you can -- I'm sure

8   there are examples, so --

9   THE COURT: But on the other part, is the drop

10   dramatic? In other words, you seem to think it all works out

11   in the wash.

12   THE WITNESS: Washes out.

13   THE COURT: Some term like that. But if one's only

14   slightly higher -- if the majority is more likely the slightly

15   higher and then the remaining are dramatically lower, what do I

16   do with that?

17   THE WITNESS: I don't have those numbers right here in

18   front of me, but what I can tell you is that those products,

19   those 24 out of 44, account for 75 percent of the spending. So

20   the ones where the 38 appear to be -- you know, I don't want to

21   make a huge amount -- it's just they're on average quite

22   comparable. If anything, it looks like, for more products and

23   for more Medicaid spending, the average amount paid per claim

24   is higher in the remaining 38. And I hope that I'll get a

25   chance today to talk about some analyses that I've done in

Page 34

1   recent months going out of samples. So let's go to some of

2   those 38 and see how they're --

3   THE COURT: So but the big difference between the

4   state and CMS data is, you don't get the MACs spelled out and

5   you don't get the differences in dispensing fees fleshed out.

6   Is there anything else that's materially different between the

7   two data seats for our purposes?

8   THE WITNESS: No. Those are the key ones.

9   THE COURT: Those are the two key ones? And so if you

10   have just the CMS claims data and you don't have the state

11   data, that would be the question mark. If you have the state

12   data, you could go back and double-check and find out?

13   THE WITNESS: That's true, yes.

14   THE COURT: So since we have the state data in 30, if

15   we had to, and I know it wouldn't be a joyful task, but if we

16   had to, you could at least analyze 20 more states along the

17   same lines that you've done for the ten?

18   THE WITNESS: And fortunately, I don't know that 20

19   more is -- I think we're in the 20s as opposed to at 30, but

20   fortunately, for the 9 states within the 38 for which we had

21   the most data, I've since done some analysis.

22   THE COURT: I see, so beyond the initial 10?

23   THE WITNESS: That's right.

24   THE COURT: I see.

25   THE WITNESS: And so we can assess that.

1   THE COURT: All right. I've stopped hijacking your

2   witness. All right, go ahead.

3   MR. LAVINE: Thank you, although I can tell that he

4   wants to continue with that exact point.

5   Q.   Describe a little more about the 9 that you were

6   discussing.

7   MR. DALY: Your Honor, I'd like to interpose an

8   objection. The situation is this: Dr. Duggan has -- well, we

9   just got some new analysis that he did last Monday after

10   Thanksgiving. He's already filed four expert reports. He

11   filed an original, he filed a supplement, he filed a rebuttal.

12   He filed an affidavit in support of summary judgment. This

13   hearing has been set for a couple months, and, you know, a week

14   before we're coming in here, we get some new apparently very

15   extensive examination that we've had some opportunity to look

16   at, but by no means the opportunity to dig in and find out what

17   it is that he did.

18   THE COURT: Well, that objection is overruled. If you

19   need a little extra time to have your expert look at it and

20   respond to it, of course I will allow that.

21   MR. DALY: Thank you, Judge.

22   Q.   Sorry, go ahead, describe the analysis with respect to the

23   9 and the outcome of that.

24   A.   So basically I sort of -- the initial report, and there

25   was a subsequent revision to it, just that revised the numbers

Page 36

1   a little bit, sort of I really tried in that initial report to

2   make it very clear where the big number, the 65 or, you know,

3   whatever the large number was, where they were coming from by

4   giving state-by-state summaries and in some cases multiple

5   summaries for each state. And so it is straightforward to look

6   at the initial report and the subsequent revision, the table, a

7   couple of the tables, to see, what did my extrapolation

8   methodology predict for the state of, for example,

9   Pennsylvania? What did it predict for the state of Virginia or

10 Texas and so forth? Because these are states for which I had

11 state-produced claims data but did not -- they weren't included

12 in the original 10. They were not in the original 10, but

13 these new 9, how does the extrapolation methodology fare?

14   So, for example, in the state of Pennsylvania, my

15 extrapolation methodology said 1.2 million, just rounding to

16 the nearest --

17   THE COURT: The difference?

18   THE WITNESS: Yes, the federal difference. My

19 extrapolation methodology said 1.2 million. And here I'm going

20 to round just to the nearest 100,000 so --

21   THE COURT: Sure.

22   THE WITNESS: And the amount doing a claim-by-claim

23 analysis -- that's apples to apples with the ones that I did

24 for the other 10 states -- 1.1. So it was a little higher for

25 that one of the 38.

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1   For Virginia, 0.9 and 0.9.

2   For Texas -- and Texas actually is interesting because

3   that was one of the states that Abbott counsel criticized me a

4   lot for not including them in the original sample -- my

5   methodology yielded 0.9 million, and the claim-by-claim

6   analysis yielded 0.9 million, in fact slightly higher with the

7   claim-by-claim analysis.

8   MR. LAVINE: I'm sorry, Judge, I should have pointed

9   out these numbers are in the last page of Tab E.

10   THE WITNESS: They're in Tab E.

11   THE COURT: All right, give it --

12   MR. DALY: Thank you.

13   THE COURT: This is very useful, but you don't have

14   it, right?

15   MR. DALY: Right.

16   THE COURT: Is this what he got last Monday?

17   MR. LAVINE: Yes. The only materials contained in

18   here are copies of the materials already produced.

19   THE COURT: Do you have an extra one for my law clerk,

20   since you seem to have volumes back there?

21   MR. LAVINE: Sure.

22   THE WITNESS: So should I resume?

23   THE COURT: Yes.

24   THE WITNESS: So here you can see a detailed, the side

25   by side of each of the 9 states. And aggregating across the

1   9 states, my methodology predicted a federal difference of

2   6.4 million, and the claim-by-claim analysis yielded a

3   difference of 6.0 million, off by 6 percent, approximately

4   6 percent.

5   I will concede that it was a little higher, that my

6   methodology was a little higher than, like, then the amount

7   that is sort of apples to apples with the amounts from those

8   original 10 states, and so I was curious about that, why is

9   that true? So I drilled down a little bit on those

10   9 states, and what I found was that in these 9 states, a little

11   more often -- so if you look between the 38 states and the

12   10 states, the frequency with which the two groups pay usual

13   and customary is almost identical. It's like 24 percent for

14   the first 10, 25 percent or 24 point something percent for the

15   other 38.

16   Why does the usual and customary share matter? Well,

17   the differences tend to be lower on claims where usual and

18   customary is paid, and I think it's best for me to give an

19   example. Suppose a formula suggests 60, but a provider charges

20   40, and my methodology says 15, okay, that if you use the

21   Abbott prices and you plug them into the Medicaid methodology,

22   you get 15, if the usual and customary were higher, then the

23   difference would be 60 minus 15, 45. But if the usual and

24   customary is getting paid, the difference is going to be

25   smaller, 25, a little bit smaller.

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1   And so it turns out that these 9 states pay usual and

2   customary somewhat more than the remaining 29. So part of the

3   reason that I'm off here at all -- I mean, I don't expect it to

4   be exact to the dollar, but part of the reason that I'm off a

5   little appears to be this, this difference between those 9 and

6   the overall 38. But I guess it's useful to know that those

7   remaining 29 look more like the original 10 than these 9, but

8   in any case, it's very much --

9   THE COURT: How do you know that?

10   THE WITNESS: In terms of this dimension of this usual

11   and customary.

12   THE WITNESS: How do you know the remaining -- in

13   other words, why wouldn't it make sense just to shift down your

14   extrapolation 6 percent in all the other --

15   THE WITNESS: Six percent across the board. So I

16   guess there would be a couple ways one could do this. One

17   could say, I'm going to shift down the extrapolation by

18   6 percent, or, alternatively, that instead of using 10, I'm

19   going to use 19 in predicting. So that would end up shifting

20   down the remaining by about 3 percent, if you do sort of a

21   back-of-the-envelope calculation.

22   But suppose even you did the 6 percent, you adjusted

23   down the remaining dollars by 6 percent. So here we're talking

24   about I'm off by about $400,000. If you revised down the

25   remaining amounts by 6 percent, the effect of that is less than

Page 40

1 a million. So taken together, it is I think about 1.3 million.

2 It's 0.4 and 0.9 would be the adjustment. So if one were to

3 apply the 6 percent across the board to the remaining 29

4 states, it would lower it by about -- the overall difference

5 from -- and let me just see if I have the --

6   THE COURT: Well, would that be a reliable

7 methodology, to take the 6 percent and apply it across the

8 other states?

9   THE WITNESS: Part of the reason that I drilled down

10 in the way that I did was to see, are these 9 -- it looks like

11 these 9, you know, paid the usual and customary a bit more

12 often than the remaining 29, who actually pay usual and

13 customary less often than the remaining 10. So I still think a

14 more accurate estimate of the total difference for those

15 remaining 38 would be the other number, but it's not -- it

16 wouldn't be -- it would be --

17   THE COURT: Well, would there be a way of going into

18 these other states and seeing whether their usual and customary

19 reflects these additional 9?

20   THE WITNESS: Right, so I think I've actually done --

21   THE COURT: You've done that.

22   THE WITNESS: Yes. So the usual and customary for

23 these 9, the statistic that I recall right here is about

24 27 percent of the time they're paying usual and customary,

25 versus about 24 percent for the first 10, versus less than

Page 41

1   24 percent for the remaining 29. But you can see, they're

2   very -- I guess the takeaway for me from this -- and I'll

3   concede that I would have preferred 6.4 and 6.4 in terms of the

4   method, like -- "prefer" isn't the right -- but I would --

5   THE COURT: You would have taken greater academic

6   satisfaction.

7   THE WITNESS: Right, in being exactly on the money,

8   but being within 6 percent, you know, this is a pretty

9   complicated set of data and so forth, it makes -- you know, to

10   me, it really corroborates the methodology that I've deployed.

11   THE COURT: So what about differences in dispensing

12   fees, which was another big point? There were some huge

13   differences.

14   THE WITNESS: In the dispensing fees.

15   THE COURT: That Abbott sort of highlighted.

16   THE WITNESS: Right, so I can -- I can -- it turns out

17   that these sort of enhanced dispensing fees for the 9, so if we

18   look among the 19 states now, the first 10 in these 9, several

19   of them have these sort of enhanced dispensing fees; and the

20   frequency with which those dispensing fees are paid is actually

21   not all that high. So in terms of, does it make a material

22   difference to the analysis, there are going to be instances

23   where it will matter on a claim-by-claim basis; but in a

24   material difference, it's not a big driver of the total

25   difference. So, you know, it is true that -- and that's

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1   something certainly that I looked at, these dispensing and so

2   forth, that they do vary to some extent across the states, but

3   in a systematic common way, not so much, that is reflected in

4   the data.

5   THE COURT: Do you want to pick it up?

6   MR. LAVINE: Yes, Judge.

7   Q.   Two quick follow-up points on the data. The SMRF/MAX

8   data, is that claim by claim that shows an individual

9   prescription in each line?

10   A.   Yes. Yes, it does, and it's -- yes.

11   Q.   So what is the difference between that and the SDUD data?

12   A.   The SDUD data, the SMRF/MAX data is very similar to the

13   state-produced claims data. It differs a bit, as we discussed.

14   The SDUD data represents the aggregate number of prescriptions

15   and total amount paid per state in a state NDC quarter

16   combination. And it's helpful, I think -- I don't know, your

17   Honor, if you have the report in front of you, but Tables 26-A

18   and 26-B give a sense of --

19   THE COURT: And this is in what, Tab --

20   THE WITNESS: Under "Reports," this would be in Tab 1.

21   THE COURT: SDUD.

22   THE WITNESS: So here are the 38 states listed in

23   descending order of spending for the complaint products, and

24   you can see in Table 26-A that the amount of SMRF/MAX data used

25   for these 38 states is about 34.5 million, and you can see here

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1   that basically all of the states have data from '99 through

2   2001, with the exception of Tennessee, which was different in

3   other ways. But there are some -- -and then there are many

4   states that go far back. For example, you know, the state of

5   Pennsylvania goes all the way back to 1992 with the SMRF/MAX.

6   But not all of the states have SMRF/MAX data in every year, so

7   on Table 26-B I list the SDUD spending and utilization for the

8   remaining state years. And the latest this data is used is

9   1998 because I have SMRF/MAX always for '99 to '01. But it

10   gives you a sense. We're talking about 13.9 million for the

11   SDUD data and 34.5 million for the SMRF/MAX for these other

12   states.

13   THE COURT: Well, so how do you extrapolate backwards?

14   How do we know that, without even the SMRF/MAX data, that

15   that's reasonable?

16   THE WITNESS: Okay, so what I do in the analysis is,

17   for each NDC quarter combination -- and there are about 2,000

18   NDC quarter combinations because there's 44 products and

19   there's 44 quarters -- I essentially take the average of the

20   10 states for which I have data and use that in these remaining

21   38 states.

22   So just as an example, just to give a sense, suppose

23   that 5 of those states have an average ratio of difference to

24   spending of 70 percent in a particular NDC quarter combination --

25   so this is really, like, this level of detail. It's not like

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1   I'm taking a state aggregate and just applying it to another

2   state aggregate. I'm drilling down to 2,000 separate distinct

3   NDC quarter combinations, taking account of the fact that these

4   spreads grew over time, taking account of the fact that these

5   spreads vary a lot across products, and respecting that

6   variation when I try to predict/estimate what the difference is

7   in another state. And so I take the average of those 10

8   states.

9   Now, admittedly, in certain periods, I don't have data

10   for all 10 states, so there may be certain and many NDC quarter

11   combinations where I only have 9 states or 8 states. But

12   underlying that in each of these NDC quarter combinations are

13   typically thousands of claims for these states. Then I'm using

14   that to predict over -- estimate for this other group. So

15   literally for every state analysis, for all -- I do 38 separate

16   state analyses where I say, how much vanco 653301 does this

17   state have in the fourth quarter of '97, and then I compare

18   apples to apples with the other 10 states, try to use that to

19   estimate that difference ratio.

20   THE COURT: Would you take an average?

21   THE WITNESS: Take an average, I take an average.

22   THE COURT: And then have you spot-checked yourself

23   the way you did with the other set of data?

24   THE WITNESS: No. So that's for the other 38. So

25   there's no need for a extrapolation back with the other 38 in

1   the sense that I'm using this average of the 10 states to

2   predict for these 38.

3   Now, for the 10 states for which I use state-produced

4   claims data -- now, there are some states where I go back

5   practically to the beginning. I think it's Illinois I have all

6   the way back to '91, quarter two. But there are others where

7   the data turns on later in the period, and so in that instance,

8   what I do -- suppose that we're in a state where the first

9   quarter data is 1996 quarter one, okay? And then for that

10   state we have excellent data, the population of claims for that

11   state in that, say, quarter. And then I calculate the

12   difference-to-spending ratio there. Say it's 70 percent, okay?

13   Now, what I could have done was just apply that

14   backwards, but that wouldn't account for the fact -- and this

15   is especially important going backwards -- that spreads are

16   growing over time. So if I extrapolated back that

17   70 percent, that would overstate the difference on average, in

18   my judgment, because it would not account for the fact that,

19   you know, the spread in '92 was a lot lower than it was in '98.

20   And you can come up with exceptions, but in general it's sort

21   of going back. And so I adjust down. So, for example, suppose

22   the spread was, you know, in that 70 percent example, suppose

23   the spread was only half as high in an earlier period, then I

24   would move that 70 to 35. Now, what's --

25   Q.   Is that phenomenon -- I'm sorry -- reflected in the

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1   Figure 1 to your initial exhibit?

2   A.   That's exactly right, so I think it's helpful to go to

3   Figure 1. What I'm essentially trying to -- it may even be --

4   it may be more useful to go to Figure 2. This would also be in

5   Tab 1. Do you have the figure in front of you?

6   THE COURT: Yes, I do, yes.

7   A.   Okay, so you can see that the published prices are going

8   up, while you can also see that the average transaction prices

9   are falling. So what this extrapolation back in time does is,

10   it accounts for that. And, moreover, if for whatever reason

11   when extrapolating back the spread were bigger, I don't account

12   for that. So I basically say, I'll only adjust it down going

13   back. So if for whatever reason the spread a year earlier was

14   a bit higher, I basically take the minimum of whatever -- so

15   I'm basically, this is accounting for this method.

16   Now, how do I probe the validity of this? And I describe

17   this in my rebuttal report. I essentially pretend for each

18   state that my data started a quarter later than it actually

19   did. And what I find when I do that is that the difference

20   using the extrapolation is lower aggregated across the states

21   than it is when I use the state claims-by-claims data,

22   consistent with the notion that it's -- essentially it's in a

23   sense conservative. It can only adjust down that difference

24   going back in time. I don't ever adjust it up, and consistent

25   with that, the pattern is that it is, if anything, having more

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1   state-produced data would lead to a higher difference.

2   THE COURT: When do MACs kick in in most states? Are

3   MACs even a factor in trying to understand this early on?

4   THE WITNESS: They become a bit more of an issue later

5   in the period, and they're certainly an issue in Ohio, but Ohio

6   wasn't in the ultimate analysis. But during this time period

7   for this set of products -- and, once again, there are examples

8   and there are cases, but systematically this is not, for these

9   products, it's not -- I don't have the number off the top of my

10   head, but what I can say is that to the extent that MACs are

11   being paid, that will be reflected in a lower difference. And

12   so that, you know, my analysis -- ultimately, you know, I have

13   this analysis that drills down the states-produced claims data,

14   uses the results from that. Really, and at some level I'm

15   using data for almost 2 million claims to form these 2,000 NDC

16   quarter averages, and then for every one of the 38 states, you

17   know, basically lining up their utilization for those 2,000 NDC

18   quarter averages and predicting and estimating what the

19   difference will be. So I'm leveraging an incredible amount of

20   data in this sample, which has, you know, almost 2 million

21   claims to estimate difference in a sample with less than a

22   million claims going across the states.

23   THE COURT: How much -- your sample had 2 million, and

24   the other states had how many?

25   THE WITNESS: 890,000.

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1   THE COURT: For all the other?

2   THE WITNESS: Other 38.

3   THE COURT: Excuse me. So the 2 million are for the

4   10 states, and the other 38 are the 890,000?

5   THE WITNESS: Yes, that's right. And I'm just looking

6   at the most recent one, so Table 35 behind Tab 2 -- Table 25, I

7   mean, behind Tab 2 gives you a sense of this.

8   THE COURT: Wait a minute. I just want to make sure

9   I've got that right. Table 35.

10   THE WITNESS: No, I'm sorry, Table 25 behind Tab 2.

11   It's the first page behind Tab 2.

12   THE COURT: All right, I was in the wrong location.

13   Okay.

14   THE WITNESS: So if you look at that first row there,

15   the total for the first set of states, 2.1 million claims.

16   It's a bit lower because some of them are SMRF/MAX, some are

17   SDUD, but if you aggregate it up, it's in the neighborhood of

18   1.8 million.

19   THE COURT: No, I'm not seeing. Where are you

20   pointing to?

21   THE WITNESS: So the third-to-last row, total for

22   first 11 states, if you look at the number --

23   MR. DALY: Third to last up and down, Judge.

24   THE WITNESS: Third to last from the bottom.

25   THE COURT: Oh, from the bottom. I'm sorry.

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1   THE WITNESS: Yes, that's okay. And so you see the

2   column that says "Number of Claims," you see 2.1 million for

3   the first 11 states. So here I would want to subtract out

4   Indiana, which is about 200,000. And, you know, when thinking

5   about this, so that brings us down to around 1.9, but, in any

6   case, you can see that the number of claims in this initial

7   10 states is about twice as high as the number in the remaining

8   38. And so I'm leveraging an incredible amount of data to form

9   an estimate of this ratio of difference to spending.

10   Q.   How does that compare to the size of a more common sample

11   that you might deal with or have seen?

12   A.   Well, I think that there are many cases where a much

13   smaller sample is used to try to learn something about an

14   economywide or marketwide phenomena. So, you know, if you

15   think of Gallup polls that are trying to predict what fraction

16   of people are going to vote for President, those are often in

17   the neighborhood of 1,000 to 2,000. But closer to this kind of

18   thing, suppose one -- there's a recent study by -- Gruber and

19   Rodriguez set out to answer the question, how much uncompensated

20   care do physicians provide in the U.S.? And they used a sample

21   of about 4,000 physicians in their analysis to learn something

22   about how much uncompensated care nationally is provided by

23   several hundred thousand physicians. So the ratio, they're

24   leveraging -- for every one physician in their sample, there

25   are, I think, 150 or so physicians outside of their sample, and

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1   there are big differences between their sample and the

2   population of physicians. So, in any case -- and this is a

3   study that was published in the Journal of Health Economics,

4   which is the leading journal in the field of health economics,

5   and it's a very highly regarded study.

6   THE COURT: I think we should keep going till about

7   3:30 and take a break.

8   MR. LAVINE: Sure.

9   THE COURT: Unfortunately for you all, I've been on

10   trial since 9:00, so I think I'll take a break for fifteen

11   minutes.

12   MR. LAVINE: I think we're covering a lot of ground,

13   so it would be helpful to take a break to reorganize anyway.

14   Q.   I want to bring you back to the SDUD data again. Have you

15   ever used the SDUD data before in your research?

16   A.   I have. In one of the papers listed in my CV, in the

17   Quarterly Journal of Economics, I use that data with -- it's a

18   coauthored paper with Fiona Scott-Morton in 2006 to look at

19   pharmaceutical prices in the U.S. and the fraction of --

20   THE COURT: Didn't she represent --

21   THE WITNESS: Yes.

22   THE COURT: -- Schering? She was in the Track One

23   trial, I think, right?

24   MR. HENDERSON: She testified at the tutorial.

25   THE COURT: She did the tutorial. Yes, I remember

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1   her. It's just an unusual first name, if nothing else, so --

2   THE WITNESS: Right.

3   THE COURT: All right.

4   A.   So in that study, we set out to estimate the effect of

5   Medicaid reimbursement rules on pharmaceutical prices

6   generally, and we used the SDU data for that. And that was the

7   lead article. The QJE is I think the most highly cited e-con

8   journal. Like, for us, that was a great publication. It's

9   been a paper that I think has people -- I think people have

10   liked it a fair amount. I think it's a pretty highly regarded

11   study. It is a well-regarded study.

12   It's also interesting because it illustrates in that

13   analysis, how did we form our sample? Well, we focused on the

14   top 200 selling drugs in the U.S., and, coincidentally, those

15   200 drugs accounted for about two-thirds of drug spending in

16   the U.S., and --

17   THE COURT: Are they branded or generics?

18   THE WITNESS: They're branded drugs. And so it's an

19   interesting study because it illustrates both the value of this

20   SDUD data and also this notion of focusing on the big, whether

21   it's in this case drugs in the current setting states, the

22   observations that are disproportionately important and trying

23   to infer something marketwide. And so it is -- yes, so that's

24   in one example. I've used the data for other work as well, but

25   that's certainly the one where it's very at the center of the

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1   analysis.

2   Q.   And the journal it was published in?

3   A.   The Quarterly Journal of Economics.

4   Q.   In a peer-reviewed --

5   A.   Peer-reviewed journal, and it was the lead article in

6   February of 2006, so at Page 1 to 31. So that was, you know,

7   it is a study that -- and it inspired us to do more work on

8   Medicare Part D and other things, but it's a -- the SDUD data

9   is great, it's terrific. It's incredibly useful data.

10   Q.   Can you go back to your Figure 2 of your original report,

11   the second page after Tab 1. There's a few different things to

12   cover. I don't know if we'll get it in in eight minutes, but

13   just quickly, what is the pink line on here? Because you have

14   it identified as an average price. What is that?

15   A.   That is the average price to the pharmacy classes of trade

16   in Abbott's indirect data, transactions that occur through

17   wholesalers and distributors.

18   Q.   And for one particular product?

19   A.   That's right, for vancomycin, which is actually, at least

20   in terms of Medicaid spending, by far the largest product of

21   the 44.

22   Q.   And you said it's limited to pharmacy classes of trade?

23   A.   That's correct.

24   Q.   Okay, how does that differ from an average for all classes

25   of trade?

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1 A.   So in a subsequent table of the report, I sort of show

2 that, sort of to get a sense of how prices vary across the

3 different classes of trade, an inspection of that data reveals

4 that pharmacies tend to pay substantially more than other

5 customers, so about 20 percent more for the retail pharmacy

6 class of trade, for example. There are a few other classes of

7 trade that are included in here, but the big one is the retail

8 pharmacy, and they're about 20 percent more than the average

9 price on average. And so, once again, there will be product

10 quarter combinations where they're less than 20 percent, others

11 where they're more than 20 percent, but on average, they're

12 about 20 percent higher than the all-customer average price.

13 Q.   And the averages you used for the pharmacy class of trade,

14 did that account for all discounts and rebates that were

15 offered by Abbott?

16 A.   It did not. It excluded some of them. So if one looks

17 at, for example, Table 7, there's this customer rebate that

18 accounts for about 7 percent, that represents about 7 percent

19 of invoice, and that was not subtracted off in that analysis.

20 So it does not account for every single rebate in the --

21 Q.   So were you pointing to --

22 A.   Table 7.

23 Q.   Table 7.

24 A.   Yes. So it is. . .

25 Q.   Now, so this is the average price. That's not the price

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1   you used in your analysis, right? Was that scaled upward?

2   A.   That's right, so there's kind of two things to think about

3   here. Pharmacies pay more on average, so by telescoping in on

4   the pharmacy classes of trade, that's going to result in a

5   higher price than using the all-customer average price would.

6   And then on top of that, I scale it by 25 percent. So what

7   that means is that -- let's take a product for which the

8   all-customer average price was 5. That 20 percent higher for

9   the pharmacy would suggest they're paying about 6 on average,

10   and then kick that up another 25 percent brings you to 7 1/2.

11   So there will be exceptions, but basically multiplying the 1.2

12   by 1.25 suggests, you know, in the neighborhood, 40, 45,

13   50 percent higher than the all-customer average price is the

14   price that I'm utilizing in my Medicaid and Medicare analyses.

15   Q.   And how does that compare, that scaled-up price, the

16   pharmacy class of trade excluding some of the impacted

17   discounts, the other 25 percent, how does that price compare to

18   the overall -- I'm sorry. The price that we're discussing,

19   it's the pharmacy class of trade, not including the impact of

20   certain discounts and rebates, and then scaled up by

21   25 percent -- can we agree, we'll call that the alternative

22   prices?

23   A.   The alternative AWPs?

24   Q.   Okay. How does that compare to the overall prices paid by

25   Abbott customers?

1   A.   On average, 40 to 60 percent higher. So 50 percent on

2   average would be about that amount, maybe even a little bit

3   more than that when one accounts for the discount issue that we

4   mentioned. So we're 50 to 60 percent. You know, and I haven't

5   looked at that distribution recently, but basically one can

6   sort of back-of-the-envelope it here. Pharmacies pay about

7   20 percent more. Rebates are about -- so just the pharmacy and

8   the 25 percent kick goes to 150 percent. And then if one

9   further accounts for the fact that I'm not including certain

10 rebates, 55, 60. I just don't have -- the hesitation of

11 adjusting beyond 50, I don't have fresh in my mind how much of

12 those rebates are pharmacy as a share. So but it would adjust

13 it up still further, so in the neighborhood of 50 percent or

14 more.

15 Q.   So by the time you scaled upward, does it match up with

16 any specific percentile of Abbott's sales?

17 A.   It's in the neighborhood typically of the 95th percentile,

18 and it's helpful -- I mean, I think here --

19   THE COURT: Could you say that in a full sentence.

20   THE WITNESS: So 125 percent of the average pharmacy

21 indirect price is generally in the neighborhood of the

22 95th percentile pharmacy price.

23   THE COURT: 95 percent of its customers are paying

24 that?

25   THE WITNESS: 95 percent are paying that or less;

1   5 percent are paying that or more. And one of the tables in

2   the report that I think is helpful in assessing this is, if one

3   looks at Table 13-B behind Tab 1, so this is just seeing how

4   does the use of 125 percent of the average pharmacy -- so, your

5   Honor, do you have it?

6   THE COURT: Yes, I've got it, and then we'll finish

7   this and take our break.

8   THE WITNESS: Okay, so the bottom two lines. So I

9   think it's useful to look at the top line. If I were to use

10   the average price for pharmacies, I get a difference in the

11   state of Illinois of about 12.5 million. If instead I used the

12   all-customer price, average all-customer price, the difference

13   would be about 12.8 million, so higher, reflecting the fact

14   that pharmacies tend to pay more. So when you plug in those

15   higher prices into the Medicaid adjudication algorithm, the

16   difference is lower.

17   Then if we just skip the next line and go to the

18   fourth line, the 95th percentile pharmacy price brings it down

19   from 12.5 to about 11.9. But that's almost identical to

20   125 percent of the average pharmacy, which is on the next line,

21   12.0. So this is for the state of Illinois. So you can see

22   this is, I think, a useful way to think about -- there are

23   other ways to summarize it just looking at the price data

24   itself, but this is all these prices. So, once again,

25   44 products, 44 quarters, about 2,000 average prices are being

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1   then used in adjudicating all of these Medicaid claims, about

2   530,000 or 540,000 Medicaid claims; and whether you use the

3   95th percentile or the 125 percent of the average, it's pretty

4   similar.

5   THE COURT: Okay, we'll take our break, fifteen

6   minutes. How much longer do you think you have? We can go off

7   the record on this.

8   (Discussion off the record.)

9   (A recess was taken, 3:30 p.m.)

10   (Discussion off the record.)

11   (Resumed, 3:53 p.m.)

12   BY MR. LAVINE:

13   Q.   Dr. Duggan, I wanted to go back to your Figure 2, the one

14   right after Tab 1. Actually, I'm not sure if this will help or

15   not, but I think the chart will help. Can you describe how you

16   considered the issue of differences between states as to

17   whether the ultimate payment was based on a MAC or a U and C

18   and how that affected your analysis?

19   A.   Can you repeat?

20   Q.   Sure. The impact of the actual payment as adjudicated by

21   the state having been based upon a MAC or a U and C as opposed

22   to an AWP --

23   A.   Right.

24   Q.   -- that was based upon Abbott's inflated list prices, how

25   did that factor into the way you handled it?

1   A.   So in terms of the claim-by-claim analyses that I did in

2   these 10 states, I guess the way to think about what the sort

3   of how my algorithm calculated this difference in each case, it

4   basically took the Abbott transaction price to pharmacies,

5   kicked it up by 25 percent, and often, very, very often that

6   would obviously fall quite a bit below the published AWP in

7   that period.

8   Now, there would be times in which the -- let's say the

9   state was paying -- a claim was being paid on usual and

10 customary, and the usual and customary on a per-unit basis,

11 take, like, '98 when the average price was about 5 and the

12 published AWP was about 70, all right, so there's a discrepancy

13 there of about 64. Suppose that the provider submitted a usual

14 and customary of, I don't know, 30 for that product, then the

15 difference, instead of being 70 minus 6 would be sort of in the

16 neighborhood of 30 minus 6 on a per-unit basis. And to the

17 extent that that happened, you know, so -- and similarly for a

18 MAC, there might be a MAC in effect of 20 or 30 or 40 for that

19 product -- to the extent that that happened, and that happened

20 quite commonly in the 10 states for which I had data, and so I

21 used the information from many, many, many claims, hundreds of

22 thousands of claims for these, you know, almost 2 million

23 claims for these 10 states, the frequency with which usual and

24 customary was being paid, MAC was being paid and so forth, to

25 sort of estimate what the difference would be in these

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1   alternative places. And so I'm not sure if I'm getting at

2   exactly what you're asking, but basically --

3   THE COURT: Well, does usual and customary vary a lot

4   state by state?

5   THE WITNESS: There is a little bit of variation.

6   THE COURT: That's what you told me about before.

7   THE WITNESS: Right, there's some variation. It's not

8   massive but --

9   THE COURT: But that was the 6 percent?

10   THE WITNESS: That is driving part of that 6 percent,

11   and quite plausibly explaining all of it, that there is a

12   little bit of variation from one state to the next in terms of

13   usual and customary, and in the aggregate, the 10 look very

14   similar to the 38.

15   THE COURT: And you could do that, if you had the

16   state-produced data, you could figure it out more precisely and

17   the second set of data, but not just if you had the SDUD data,

18   or whatever you call it.

19   THE WITNESS: The SDUD data, right.

20   THE COURT: The SDUD data.

21   THE WITNESS: The SMRF/MAX you can absolutely do it.

22   THE COURT: Right.

23   THE WITNESS: The SDUD data, to the extent that it's

24   going on, it's going to be reflected in lower amounts paid, so

25   it's to some extent --

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1   THE COURT: You just won't know why?

2   THE WITNESS: Right, that's right. Is it a usual and

3   customary, or is it some other factor in the SDUD data? But

4   that's why I sort of combined the empirical analyses of the

5   millions of claims with an examination of the adjudication

6   methodology that's used by the various states. And, I mean, if

7   there's any part of Medicaid reimbursement, you know, where

8   there's -- there's always differences across states because

9   there are 50 state Medicaid programs, 51 state Medicaid

10   programs the states administer, but the similarity with respect

11   to pharmaceutical reimbursement during this time period is very

12   high. If I were doing this for nursing home reimbursement or

13   the reimbursement of physicians or something else, there is

14   more heterogeneity on those mentioned. But in terms of

15   pharmaceutical reimbursement, the frequency with which states

16   are AWP minus 10 with a dispensing fee, and there are wrinkles

17   also to it, but the examination of the methodology indicates

18   between the 10 and 38 just a great deal of similarity.

19   THE COURT: And do they all have MACs?

20   THE WITNESS: Do they all have MACs? For these 44, I

21   don't believe so during this period, no. But I don't have that

22   particular one at my fingerprints, but I think, as time wore

23   on, states became more and more -- there's kind of two things

24   going on: Does a state have a MAC program or not? Then how

25   many of the -- I think at any point in time, there are 25,000

1   NDCs being reimbursed by Medicaid. And so whether it applies a

2   MAC to a specific NDC, even if a state has a MAC program in

3   effect, that doesn't mean that it does for these products. So

4   it is not -- there are certainly some states, to the best of my

5   recollection, that do not have MACs for these products during

6   the period.

7   Q.   Well, specifically, what was the impact of the lesser-of

8   methodology in connection with this issue?

9   A.   Right, so the lesser-of methodology, the states are

10 similar in the sense that if the formula, AWP minus 10 plus a

11 dispensing fee, let's say, generates 60, but the pharmacy

12 charges 40, the state is going to pay the lesser of those two

13 amounts. And so that's one very important respect in which the

14 states are similar on that dimension. So that lesser-of

15 methodology is going to result in a lower difference-to-

16 spending ratio than would result if it was solely driven by the

17 formula. It's going to tend to -- for the claims paid on usual

18 and customary, all else equal, they're going to tend to have

19 lower paid amounts, and so that's going to be reflected in a

20 lower difference. But that's very common. As I said, it's

21 about 24 percent of the time usual and customary is being paid

22 on these 10 versus about 24 or 25 percent in the remaining 38,

23 so it's common.

24 Q.   But if the alternative price were higher than the basis of

25 reimbursement, regardless if it was based on a MAC or a usual

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1   and customary, would you have calculated any difference in that

2   situation?

3   A.   No.   So suppose that the usual and customary in that 1998

4   example, suppose they had submitted, let's say, for this vanco

5   product one unit, an average price of about 5, add that to a

6   dispensing fee of, let's say, 5, so that's a $10 prescription.

7   If the pharmacy had charged $9, zero difference, no difference.

8   And in fact there are a decent number of claims for which there

9   is no difference, and it's actually more common among those

10 claims paid at usual and customary. So if you look at the

11 claims that are paid based on the adjudication, like the AWP

12 minus 5 or 10, those, I mean, not surprisingly looking at this

13 figure, if they're basing reimbursement on AWP, it's pretty

14 much always -- not always, but it's rare that the difference is

15 zero, but for usual and customary, it happens a decent amount.

16 Q.   What is Tab 4 in the materials that you have in front of

17 you?

18 A.   So this is a summary of the adjudication methodologies

19 used by each of the states, and at my direction, Myers &

20 Stauffer compiled this information from a variety of sources,

21 as indicated in the color-coded bars just below the graph. So

22 there's a lot of detail here on how states are reimbursing,

23 and, you know, one can see that the methodologies do change to

24 some extent over time within the states, and that, you know, it

25 provides data on -- am I looking at the right thing? -- it

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1   provides data on the methodology.

2   THE COURT: Do you know how to use this document

3   camera?

4   MR. LAVINE: No. I have not used this, Judge.

5   THE COURT: Robert, will you show them.

6   THE CLERK: It's just an overhead projector. Put the

7   thing on it. It should be on.

8   (Discussion off the record.)

9   THE WITNESS: So this is a detailed description of the

10   adjudication methodologies that were in effect in each of the

11   states during the time period of interest, telling things like

12   what is the estimated acquisition cost, what is the standard

13   dispensing fee and so forth. And there's many components of

14   information here, but I made good use of these in carrying out

15   the analyses that are summarized in my report and in subsequent

16   rebuttal report and so forth.

17   THE COURT: And you are defining usual and customary

18   as what, just the bills charged?

19   THE WITNESS: Yes, how it's coded in the state data

20   varies from one state to the next, but it's essentially the

21   pharmacy-charged amount.

22   THE COURT: And in other cases, since I have so many

23   of these, I learned that they tend to track AWP. Would you not

24   agree with that? In other words --

25   THE WITNESS: They tend to go up.

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1   THE COURT: As AWP goes up.

2   THE WITNESS: It is my recollection actually, I think,

3   that -- so the following statistic would be consistent with

4   that, which is to say usual and customary is paid less often

5   over time, suggesting that it's going up perhaps even a little

6   more. I'm not sure, but certainly I do think that it tended to

7   increase over time despite --

8   THE COURT: It's less than AWP but usually more than

9   the prices that people pay?

10   THE WITNESS: More often than not it's above AWP, what

11   they're submitting as the usual and customary, because more

12   often than not -- because remember I said that about --

13   THE COURT: You would say U and C is usually above

14   AWP?

15   THE WITNESS: It is, in many cases it's above, so

16   because it's a lesser-of methodology that's used, and so the

17   formula, let's say AWP minus 10 in a particular state, that is

18   more often paid than the usual and customary amount. In some

19   cases, some states, the provider may not submit it. It's going

20   to vary.

21   THE COURT: So that's consistent, actually, because if

22   one is U and C, it's not U and C minus 10 percent.

23   THE WITNESS: That's right, that's right. So it could

24   be right at AWP, they could be charging exactly AWP, but it

25   wouldn't be paid, given that. But, as you can imagine, this

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1   was not something that Myers & Stauffer did in an afternoon.

2   This took a considerable amount of research, and they really

3   put an enormous amount of work into this. And then I made good

4   use of this in the analyses in my report and in comparing and

5   sort of assessing the comparability of the initial 10 states

6   with the remaining 38.

7   So, for example, I believe the frequency with which

8   the first 10 used AWP for most of the period, I think eight of

9   the ten used AWP for most of the period, and 30 of the

10   remaining 38 used AWP for most of the period, and it's like the

11   exact same ratio, 80 percent in both cases. So that's an

12   example of the kind of thing that I was able to gauge the

13   comparability of looking across these two different -- across

14   these methodologies.

15   MR. LAVINE: Your Honor, could we have Attachment 4

16   marked for identification, please.

17   THE COURT: Why don't we have this whole binder marked

18   for identification.

19   MR. LAVINE: Oh, I'm sorry, sure, the whole binder. I

20   misinterpreted my colleague's request.

21   THE COURT: It's not been filed separately like this,

22   has it?

23   MR. LAVINE: No. No, the Exhibit 4 was filed as part

24   of our summary judgment exhibit.

25   THE COURT: Yes, I have a crate upstairs, so let's

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1   just put this in a succinct form, and we'll mark it 1 for

2   Identification.

3   (Exhibit 1 marked for identification.)

4   THE COURT: All right, let's just pick up speed here,

5   even though I know I've been the one slowing you down.

6   Q.   So at some point you concluded that the 10 states were

7   sufficient. How did you decide that they were enough?

8   A.   That the 10 states --

9   Q.   What types of things did you consider? How did you get to

10   that point?

11   A.   Well, there are a number of things that I considered, so

12   these adjudication methodologies, that's one of the things that

13   I considered in assessing this. And, additionally, that

14   comparison of the average paid amount per claim between the two

15   sets of states suggests that they are quite comparable.

16   Additionally, I think it's worth noting that the analyses

17   that I do take into account -- so states are going to differ

18   with respect to which of the 44 products they're reimbursing

19   for, and so the analysis takes that into account by looking

20   within each of these NDC quarter combinations 2,000 different

21   NDC quarter combinations, accounting for the fact that it just

22   may be the case that Vermont doesn't use much vanco, whereas

23   New Hampshire uses a very large share of vanco, like, it

24   accounts for a disproportionate share.

25   So not only did I do a number of things to assess the

1   comparability of the adjudication methodologies, the paid

2   amounts that resulted and so forth, but similarly, to the

3   extent that there were differences in terms of the pattern

4   across products or the pattern over time, I'm accounting for

5   that because there is definitely heterogeneity on that front.

6   And that's what makes this CMS data so valuable is that I'm

7   not -- you know, I'm basically taking into account these 2,000

8   different sets of heterogeneity, which is, you know, it's a

9   standard thing that is done to adjust for any differences

10 between a sample and the larger population. That's exactly the

11 kind of thing I'm doing. So to the extent they differ, I'm

12 accounting for that with this methodology, but broadly the

13 methodologies are quite similar.

14 Q.   Is it common to use nonrandom samples in your field?

15 A.   Definitely, and while doing it, to take care, if one wants

16 to infer more about the larger population, to take care that,

17 you know, it's sort of a fundamental issue: Is the sample at

18 hand representative of the larger population? And to the

19 extent that it isn't perfectly representative, you know, there

20 are standard adjustments. That Gruber-Rodriguez paper that I

21 talked about at the outset, for example, they take account of

22 the fact that in their sample they have relatively many from

23 California and relatively few in small practices and so forth,

24 and adjust accordingly to say something about the U.S. as a

25 whole. And again and again people are getting, you know,

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1 economists get data for one firm or a number of firms, or, you

2 know, it's one state or a multiple small number of states, so

3 it is quite common to use nonrandom samples.

4 Q.   You're referring to the study entitled "How Much

5 Uncompensated Care Do Doctors Provide"?

6 A.   That's right, that's right.

7 Q.   What was the basis of the sample that was used in that

8 case? Do you remember?

9 A.   So the sample, I think in the U.S. there's on the order of

10 about 600,000 physicians, plus or minus, depending on how you

11 count them. I think that's -- maybe four -- I don't know, it's

12 a large number. In their sample they had about 4,000

13 physicians, and these were physicians that contracted with a

14 particular claims processing company, and so they were using

15 data for a very small share of all physicians to leverage that

16 to say something about physicians in the U.S. as a whole.

17   And, moreover, they didn't have -- in this project, this

18 report, I have an incredible amount of data for this group to

19 which I am extrapolating. I have the CMS SMRF/MAX data, the

20 CMS SDUD data. That is much more than people typically have

21 when extrapolating to a larger population. So in terms of

22 the -- I mean, it's a much smaller sample. In fact, their

23 sample looks much different from the larger population than my

24 sample does.

25   And I think it's fruitful in thinking about this, one can

1   say, well, it's 10 states; but it's 10 states, it's 44 products

2   and 44 quarters. So at some level, you know, it's up to 20,000

3   different state NDC quarter combinations with many claims

4   underlying them, so a lot of information there.

5   Q.   Well, could you have used a random sample in this case?

6   A.   So it would have been theoretically possible, but one of

7   the constraints here was the issue of certain states did not

8   produce data. So I think maybe it's Oregon they did not

9   produce data. And so if I had randomly sampled from those

10   3 million claims and an Oregon claim had come up, I would not

11   have been able to use that from the state-produced data.

12   And similarly, the sort of issue here, there's an enormous

13   fixed cost associated with mastering the data sets, the

14   Medicaid data sets, because each state differs with respect to

15   how they code the claims. And so doing each additional state

16   takes an enormous amount of work. And part of what as an

17   economist -- you know, as a trained empirical economist, I've

18   done work with a lot of large-scale data sets -- one has to

19   determine where do you draw the line because one could be

20   engaged in the process of data collection ad infinitum. We can

21   always get more data somehow with so many applications.

22   THE COURT: How much would it cost to do each one of

23   the remaining states that we have the claims-by-claims data

24   for?

25   THE WITNESS: Well, we've done now 9 of them, and

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1   these are the 9 that we have the most data for. And so of the

2   remaining, I think like Hawaii, we may have one year of data

3   for Hawaii, so we didn't pay the fixed cost of -- but, you

4   know, it certainly would be possible. It's going to depend.

5   Some states are really straightforward, so you get the data and

6   it's a -- it varies a little bit from one state to the next,

7   but I don't have a good sense right now of the time. But, I

8   mean, part of the reason we went to considerable lengths to

9   sort of -- you know, there was this claim that the

10   extrapolation methodology was not valid, so we subjected it.

11   We said, all right, I'm going to do this analysis to get that

12   state, download that state-level data and do that analysis and

13   subject the data --

14   THE COURT: So if you add in the extra 9 states from

15   the 10, how many claims did you evaluate? I know there were

16   2 million for the first 10.

17   THE WITNESS: Right. So we're talking about. . .

18   Let's see, let me go back to where -- I'll try to do this.

19   In Pennsylvania alone is another, that's 50,000

20   claims; Texas is another 60,000 claims; Virginia is another

21   60,000 claims. So right there, that's 121-70 right there.

22   Connecticut is another 35,000 claims, so 205. Massachusetts is

23   another 39,000, so 245. Maryland is another 70,000, so over

24   300,000. So over 300,000 claims, and then Minnesota, Iowa, and

25   Utah, between 300,000 and 400,000.

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1   THE COURT: So that's 2.4, and then you would subtract

2   those from the ones -- so remaining would be in the vicinity of

3   400 and --

4   THE WITNESS: No, I think remaining would be -- let's

5   say, of the remaining, so in Table 25, 900,000. Let's say

6   there's 350 in the sample of 9 states, 350,000, so remaining,

7   maybe 550 claims for the remaining --

8   THE COURT: That hadn't been analyzed to 2.4 that had

9   basically?

10   THE WITNESS: Yes. So it is -- yes, that's right.

11   Q.   I just want to touch on one last Medicaid issue. On the

12   intrastate extrapolations where you take from one year to

13   earlier years in that same state, can you just quickly walk

14   through that, maybe using Michigan where you had five quarters'

15   worth of data?

16   A.   Right, so this is the case in which -- I'll just go

17   through it quickly because we did it a little bit. Basically,

18   for each of the 44 products, in Michigan, for example, I would

19   take the difference-to-spending ratio for each product in that

20   first quarter, 2000 quarter four, and then project it

21   backwards, but scaling it only down, only down to account for

22   the fact that the spreads tended to grow over time. So that

23   70 percent ratio for a vancomycin product, let's say, in 2000

24   quarter four, it's going to just walk down to probably

25   40 percent by the beginning of the period because the spreads

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1   then were, instead of like 15 to 1, were more like 8 to 1. So

2   it's going to cut it roughly in half, the --

3   Q.   And moving backwards, did you utilize the Myers &

4   Stauffer's methodology summaries that we talked about on

5   Exhibit 4, and did you look at the SDUD and the SMRF/MAX data

6   to see if it was comparable, things like that?

7   A.   Absolutely, so I sort of inspected whether and to what

8   extent, looking back in time, it was appropriate to deploy, you

9   know, to use this ratio. And, you know, once again, it's

10   possible there's an example here and an example there, but

11   across the board, the methodologies -- I mean, the neat thing

12   about using those state-specific NDC quarter combinations is

13   that those are going to be the same pharmacies being reimbursed

14   in those earlier periods. So it's a useful, but I certainly

15   did probe that issue.

16   Q.   Just to try to cover the rest of the issues, let's switch

17   to Medicare. You did two types of extrapolations there, right?

18   A.   Correct.

19   Q.   Was all the Medicare data that you utilized claim-by-claim

20   data?

21   A.   Yes. In terms of information on spending and number of

22   claims, I combined it with array information, data on arrays.

23   But there was only one data set. There wasn't a state-produced

24   SMRF/MAX/STUD analog. It's just the Medicare claims data.

25   Q.   And that is claim-by-claim data?

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1   A.   Correct.

2   Q.   Okay, no aggregate data there?

3   A.   Right.

4   Q.   So the issue for the extrapolation related to the arrays

5   on the Medicare side?

6   A.   I guess I would -- I mean, I would just say that there are

7   two types of Medicare claims before going to the extrapolation.

8   One type are the DME claims for which I'm not doing an

9   extrapolation. I'm using --

10   THE COURT: Durable medical equipment?

11   THE WITNESS: Right, durable medical equipment, that's

12 right.

13   THE COURT: You're not doing that?

14   THE WITNESS: No, no, I'm using those claims, but I

15 have arrays that cover the period. There's another set of

16 Medicare claims, the Part B claims, the carrier claims, for

17 which I am doing some extrapolation. Those claims are

18 summarized in Table 34. But I do think, your Honor, I think

19 it's helpful to look at Table 34 for a moment.

20   THE COURT: Table 34 is?

21   THE WITNESS: It's behind Tab 1, and it's the summary

22 of Medicare carrier claims. Okay, so do you have that in front

23 of you?

24   THE COURT: Yes. Why don't you put it up on the

25 document camera. We're going to make you high-tech by the end

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1   of this hearing.

2   MR. LAVINE: My office is going to make fun of me

3   because I'm supposed to be the high-tech guy.

4   THE WITNESS: This table is, I think, helpful just

5   getting a big picture on the Medicare data. So $185 million in

6   Medicare spending during this eleven-year period on the -- I

7   think it's eleven J-Codes that are listed in the complaint.

8   Okay, so right off the bat, one thing worth noting is that I

9   examined five of the eleven products, which are the first four,

10   70-50, 70-40, 70-30.

11   THE COURT: Where are you looking?

12   THE WITNESS: I'm sorry. The leftmost column of

13   Table 34. Okay, so they're listed there. This table --

14   THE COURT: Oh, you're reading the J-Codes.

15   THE WITNESS: That's right, the J-Codes. So this

16   basically tells you that almost $100 million in the spending

17   was for J 70-50 and about $26 million for J 70-40, and so forth

18   down the line.

19   And so I restrict attention only to the top four and

20   to J 33-70. The top four is sodium chloride, the J 33-70 is a

21   vanco product, and essentially difference equal to zero for the

22   other six. So even before getting into extrapolation, it's

23   worth noting that those six products, once again, it's sort of

24   drawing the line, time limitation type of thing. Assembling

25   the arrays from the carrier documents and so forth takes an

1   enormous amount of time, and here I focused on just five of the

2   eleven products, so the majority of products were excluded.

3   And rather than trying to extrapolate across products, I did

4   not. I could have come up with a difference from these five

5   and extrapolated it to the other six, but recognizing that

6   there's heterogeneity across products and so forth, I didn't.

7   So those claims are ignored in the analysis. The difference is

8   set to zero for them.

9   So right off the bat there is, in terms of the total

10   amount of spending, it's more than $20 million of those

11   $185 million, so I think it's about $22 million. So about

12   12 percent of the spending -- I'm doing this a bit on the fly

13   in my head, but I think about 12 percent of the spending, just

14   I set difference equal to the zero right off the bat. So I

15   just wanted to make that point before going to the discussion

16   of any extrapolation.

17   Q.   Can you remind the Court how the arrays came into play in

18   connection with setting the allowed amount for a Medicare

19   claim.

20   A.   Sure. So for any of these products, the key distinction

21   between Medicaid and Medicare, if there's one thing to remember

22   about Medicaid and Medicare, Medicare, instead of paying based

23   solely on the AWP, let's say, of an Abbott product, for these

24   J-Codes, typically carriers used AWPs for multiple firms'

25   products and then took the median.

1   THE COURT: And J-Code is when you have therapeutic

2   equivalents, generic?

3   THE WITNESS: That's right, that's right. And

4   basically the way these arrays work is, and, you know, there

5   are inevitably little exceptions here and there, but in general

6   the methodology takes the median of the generic prices --

7   THE COURT: Of all of them? That's what I couldn't

8   figure out. Of all the equivalent generics?

9   THE WITNESS: Well, there's a little bit -- there's

10 some variation across the carriers with respect to which

11 products get included in the arrays. So, you know, one carrier

12 might include -- there's a huge amount of similarity, but when

13 you look at, let's say, the array in '98 for Wisconsin

14 Physician versus Connecticut General, you know, they may both

15 have seven products in their array, and five or six may be the

16 same, but there may be one or two that differ. But it's not

17 necessarily the case that all products are included. In fact,

18 more often than, not all of the equivalent products are

19 included, but a very large number are included.

20   And so these arrays allow me to determine -- let's

21 pick a particular quarter, '97 quarter four. Suppose I have

22 the array for J 70-50, and let's say there are five products in

23 that array, two Abbott and three other firms' products. And

24 let's suppose just for simplicity that those prices are 8, 9,

25 10, 11 and 12, with Abbott at 11 and 12. They don't have to.

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1   They could be a third, 8 and 9; it won't have any effect on the

2   median. Suppose they're the 11 and 12 in that example. So

3   initially with their initial AWP the median is 10.

4   Okay, now suppose that one plugs in the price, that

5   pharmacy, 125 percent that I described earlier in for the

6   Abbott prices, they typically will fall below, often below --

7   in that example would fall below the eight. And so the median

8   would fall from 10 to 8. But it's not a one-for-one change,

9   which is to say, if you lower the AWP from 10 to 5, often with

10   Medicaid reimbursement you essentially cut in half the

11   spending, the (Inaudible) dispensing fee for a second. Here --

12   THE COURT: Here you're moving down the median.

13   THE WITNESS: You're just moving down the median, but

14   it's affecting all of the claims with that J-Code. So it is

15   a -- right, so basically using arrays, using an enormous amount

16   of array information that was assembled by Myers & Stauffer, I

17   determined how for many of these J-Code quarter carrier

18   combinations, how do alternative, you know, transaction-based

19   AWPs for Abbott products, how do those influence the median,

20   and then run that through the Medicare claims. So you can see

21   here there are 22 million, a lot more Medicare claims than

22   Medicaid claims, 22 million Medicare claims; essentially figure

23   out for each carrier J-Code quarter combination, what's the

24   effect on the median; and then see how claim by claim the paid

25   amount differs between -- you know, when you use that.

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1   And in some cases it won't be affected. So, for

2   example, if in that earlier example Abbott had the AWPs of 8

3   and 9, if you lowered their prices, it would have no effect on

4   the median, okay, because it's basically the middle price of

5   the five. And no matter what you do to these two prices, that

6   it's not going to move that --

7   THE COURT: Well, will you always know Abbott -- what

8   if Abbott is not in the array at all?

9   THE WITNESS: Then no effect.

10   THE COURT: So how would you know when you're

11   extrapolating whether in any given situation Abbott was in the

12   array and counted?

13   THE WITNESS: Right, so in this case, so initially,

14   analogous to the Medicaid, basically for the carrier J-Code

15   quarter combinations where I have an array, I run the algorithm

16   to figure out what is the difference versus what spending would

17   have been. Now let's think about other carriers first, like

18   the Vermonts from that earlier example. So one approach would

19   have been to simply take the averages for each of the J-Codes

20   and apply it to the other, the difference-to-spending ratio;

21   suppose the difference-to-spending ratio was 20 percent for one

22   of the J-Codes, apply that to the carriers for which I do not

23   have an array, the claims for the carriers where I do not have

24   an array. That would have been an approach.

25   However, in the same way that I probed on the

1   comparability of my sample and the larger population for

2   Medicaid, I do it here as well. And how do I do it? You know,

3   if I don't have the array, what can one do? What I can see,

4   for each claim, whether the allowed amount is itself an Abbott

5   AWP. So for those J-Code carrier quarter combinations where I

6   have the array, in many instances an Abbott AWP is the median.

7   And so by definition, in those cases, the median moves because

8   when you adjust AWP at all, it always goes down.

9   THE COURT: But that's when you have the data?

10   THE WITNESS: That's when you have the data. Now,

11   but, having the claims data, having these millions and millions

12   of claims for other carriers, I can see, well, what about them?

13   How often do they have an Abbott AWP as the median? And so I

14   can gauge whether and to what extent. So how often is it the

15   case that an Abbott AWP is the allowed amount in the claim for

16   that carrier in that quarter.

17   THE COURT: I see. So you might not have the array,

18   but you'll see, bingo. Now, suppose you don't have that.

19   THE WITNESS: No, I do because I basically

20   assembled --

21   THE COURT: So suppose it's not Abbott's AWP.

22   THE WITNESS: Right, and more often than not it's not

23   Abbott's AWP. And so what I figure out is that for about one

24   in four claims in the array, in those -- I hate to keep saying

25   this, but I just want to be as precise as possible -- for those

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1   J-Code carrier quarter combinations where I have data, the

2   Abbott AWP is the median about 24 percent of the time. About

3   one in four of those cases has an Abbott AWP as the median.

4   Turning to the remaining carriers during a comparable

5   period, for them it's about 16.5 percent, so it's less common.

6   And that indicates to me, given my familiarity with these

7   arrays and my work, you know, with this kind of data before,

8   that the intensity with which the remaining carriers are using

9   Abbott AWPs is lower. And so in essence, rather than simply

10 taking the ratio for those initial carriers and applying it to

11 that other group, I see there's a difference between the two,

12 it is not the case that the population in my sample is fully

13 reflective, fully representative of the greater population, and

14 so I adjust down the numbers accordingly, scaling down

15 essentially by two-thirds to account for the fact that the

16 Abbott AWP is 50 percent more common, more frequently the

17 median in the -- feel free to stop me at any point. I'm trying

18 to --

19   THE COURT: It's late in the day, and I'm trying to

20 focus myself.

21   THE WITNESS: So here the earlier case, the Medicaid

22 case, I said, let's look at the 10 versus the 38; and they're

23 really comparable, and it's reflected in this subsequent

24 analysis that I did.

25   THE COURT: Right.

1   THE WITNESS: These carriers, the Wisconsin Physicians

2   where I have the data versus the carriers where I don't have

3   the data, it is clear -- and you can imagine there was a

4   considerable amount of work that went into figuring out, is

5   this an Abbott, are these Abbott AWPs or not? And, you know,

6   there are some cases, some example here or there where in the

7   same quarter an Abbott product had the same AWP as another

8   product, but that's going to happen in both data sets. I can

9   tell you from having looked at dozens and dozens of arrays that

10   Abbott AWPs are often the median. And so --

11   THE COURT: You said a quarter of the time, right?

12   THE WITNESS: A quarter of the time, that's right.

13   And so I basically take the results for those initial carriers

14   and scale them -- so rather than taking that difference ratio

15   for the initial group of carriers, I scale it down by

16   approximately a third.

17   THE COURT: Where did you get that?

18   THE WITNESS: Or a fourth. It's basically it

19   represents the --

20   THE COURT: Where are we?

21   THE WITNESS: We're in the neighborhood of Page 124 of

22   the report.

23   THE COURT: That's the first --

24   MR. LAVINE: Tab B.

25   THE COURT: All right.

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1   THE WITNESS: So in Equations 10 and 11 on Page 125,

2   I'm describing here basically how I'm calculating the

3   difference for J-Code J and Carrier K over the period of

4   interest. So I apologize, I don't want to forget the equation.

5   So just the big picture --

6   THE COURT: Others are probably more astute right now.

7   I'm counting on my law clerk who wasn't sitting through this

8   trial this morning. So just in plain English, you've got a

9   quarter that are the same.

10   THE WITNESS: Yes.

11   THE COURT: So you can extrapolate across the

12   carriers.

13   THE WITNESS: Right. A quarter in my sample have

14   Abbott AWPs. A sixth or less -- I'm getting the numbers

15   confused, but less for the other sample. So I've got a sample;

16   there's a population. For the other carriers where I don't

17   have arrays, they have Abbott AWPs less frequently.

18   THE COURT: So it's only a sixth of the ones you don't

19   have the data for are actually compensating at what the Abbott

20   one is?

21   THE WITNESS: Exactly. And I should note that for

22   every time that an Abbott AWP is the median, there are more

23   than two where they're above the median and affected. Do you

24   see? So it's not like by knowing -- it's not like only in one

25   in four cases is Abbott affecting the median. There are a heck

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1   of a lot of cases where they're above the median, but this is

2   just a measure of the intensity.

3   THE COURT: So a sixth don't -- only a sixth are AWP

4   of the other --

5   THE WITNESS: Of Abbott, yes.

6   THE COURT: Of the other five-sixths, how do you

7   figure out whether Abbott matters?

8   THE WITNESS: Right, so the assumption, the

9   identifying assumption here is that the pattern that holds

10   within the arrays for which I have information, so for every

11   one time -- I don't have this number right here in my head, but

12   suppose that for every one time that an Abbott AWP is the

13   allowed amount, there are two where they -- two different

14   claims where they're not the allowed amount, but they affect --

15   but affect -- changing their AWP affects the reimbursement

16   amount.

17   THE COURT: They're higher than the array.

18   THE WITNESS: They're higher than the median, right.

19   THE COURT: So you're just assuming that that's gong

20   to be the same --

21   THE WITNESS: That pattern holds for the remaining --

22   THE COURT: That the pattern holds. And how do you

23   test that to see if it's true?

24   MR. LAVINE: Can I just slip in one question?

25   MR. DALY: No.

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1   MR. LAVINE: It will help.

2   Q.   Where you did have the arrays, how often was there an

3   Abbott product, an Abbott AWP?

4   A.   The vast, vast majority of the cases when, for these

5   sodium chloride and these vanco J-Codes, when there is an

6   array, an Abbott product is in there, so the vast, vast

7   majority of cases. And it is true, I mean, one can see from an

8   examination of -- if one looks at Table 43, so this is also

9   after Tab 1 --

10   Q.   The next-to-the-last exhibit for that tab.

11   THE COURT: All right.

12   A.   So for Connecticut General, you see the first line there

13   summarizes the results of the analyses for the J-Code quarters

14   where I have array information. I have data for the whole

15   eleven years, but for Connecticut General, there are about

16   540,000 claims in that last five-year period in which

17   the -- 540,000 claims, okay, for the five J-Codes that I'm

18   considering that are listed in the title of the table.

19   Now, of those, if you look one column to the left, you see

20   about 470,000 claims in which paid amount would fall if

21   Abbott's AWPs were replaced by 125 percent of the average

22   pharmacy. So that's 86 percent of claims where there's

23   differences greater than zero, okay.

24   Now, going back to that 24 percent, now, remember, the 24

25   isn't Connecticut General specific, but suppose it was. So

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1   24 percent of the time Abbott's AWP is the median, okay; and in

2   essentially all of those 24 percent of cases, moving their AWP

3   is going to lower the allowed amount because the AWP always

4   falls when you use the transaction-based price.

5   THE COURT: So you extrapolated that percentage.

6   THE WITNESS: Exactly. So basically I say 24, and

7   let's say there's another 62 percent, so that's about two and a

8   half claims where Abbott is above the median but not the median

9   for every one. And the methodology, basically the assumption

10   underlying the methodology is that that pattern holds in the

11   remaining carriers, and it is --

12   THE COURT: How did you test that? Like, you could

13   test the last one.

14   THE WITNESS: This, for example, with pulling in this

15   new Medicaid data, it is --

16   THE COURT: How do you know if that's right, there are

17   consistent patterns across the carriers?

18   THE WITNESS: Well, it is worth noting that the

19   carriers are basically operating under the same CMS guidelines

20   throughout this period, and it is true there's variation across

21   the carriers.

22   THE COURT: There was some OIG report that talked

23   about it, right? Or was that in a different context?

24   THE WITNESS: It may have been. Yes, maybe my mind is

25   getting tired now too.

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1   MR. LAVINE: That was a Medicaid issue.

2   THE COURT: That was Medicaid?

3   THE WITNESS: So the identifying assumption of this

4   methodology is -- now, it's worth noting that this isn't

5   information for just four or five carriers. This is

6   information for -- actually, as you can see here listed, there

7   are several.

8   THE COURT: So you average the pattern?

9   THE WITNESS: Yes, I averaged the pattern across the

10   time periods because it bounces around a fair amount from one

11   period to the next. Things bounce with the Medicare somewhat

12   more than with the Medicaid where it's all driven by the Abbott

13   AWP. So essentially the methodology aggregates the information

14   from dozens of arrays. Now, it does it product by product, so

15   J-Code by J-Code, but it aggregates the information because,

16   for example, vanco tends to have a bigger difference because

17   its disparity from the other ones tends to be larger than for

18   sodium chloride. So it basically aggregates that information

19   across many, many arrays, and essentially aggregates the

20   information across those many, many arrays and uses, leverages

21   all the information -- in the case of Connecticut General,

22   540,000 claims, a million claims for Wisconsin physician and so

23   forth -- to estimate for the remaining claims.

24   Now, I should also note that in doing this, recall,

25   there are a whole number of things that I'm excluding from

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1   this. For example, those six J-Codes initially, I don't

2   extrapolate to them.

3   THE COURT: How many carriers did you have full data

4   for?

5   THE WITNESS: Full data for? Well, for the entire

6   eleven-year period?

7   THE COURT: I guess I asked that incorrectly. So

8   let's assume -- how many carriers are there all together?

9   THE WITNESS: There are -- well, it depends to some

10   extent on how you count them because there are multiple -- if

11   you go back -- and I apologize for continuing to push your

12   Honor from one table to another, but -- so if one goes to

13   Table 35, this provides information. And do you have

14   highlighted in yellow?

15   THE COURT: Yes.

16   THE WITNESS: So highlighted in yellow are the

17   carriers for which I have array information, and in white are

18   the ones for which I do not have array information.

19   THE COURT: So you probably have slightly less than

20   half?

21   THE WITNESS: Slightly less than half, that's right,

22   in terms of -- I'm just going to go to -- slightly less than

23   half, that's right.

24   Q.   Are some of the carriers listed multiple times?

25   A.   That's right. So Connecticut General you can see is

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1   listed in both the -- maybe that's the 7th line and the 8th

2   line. So there are some of the carrier numbers, like one

3   carrier, the Connecticut General arrays are used for

4   Carrier 54-40, for Carrier 55-35, and so forth. So this

5   overstates -- if you think about -- it depends on -- think

6   about the carriers in terms of their numbers, if this is the

7   right figure, if you think about it in terms of --

8   THE COURT: So if in any quarter you had too few

9   carriers that you had data for, did you say, "I don't have

10   enough to know a pattern"?

11   THE WITNESS: So it's certainly true that I dropped

12   claims where the data did not suggest it would be appropriate

13   to extrapolate, so certainly for those six J-Codes we talked

14   about, but also extrapolating back in time, I -- so if we go

15   back to the Table 43, you'll see that, for example, for

16   Connecticut General, I only went back to early '95 because my

17   scrutiny of the data for Connecticut General in the first four

18   years of the period suggested to me -- I didn't see enough

19   Abbott AWPs then, so I didn't extrapolate back during that

20   period. And similarly, for those remaining carriers, I ignored

21   the first part of the data set because, once again, the Abbott

22   AWPs were less common in '91, '92 and so forth because I don't

23   have arrays in '91 and '92.

24   THE COURT: It sounds like you're making far more

25   subjective judgments with respect the arrays than you really

1   would of the Medicaid. In other words, what's enough to be a

2   pattern, what isn't? Do I have enough data, don't I? And

3   there's no way to test it.

4   THE WITNESS: Well, I think it's useful to sort of see

5   how the difference-to-spending ratio differs between my sample

6   and the population to which I'm extrapolating. So, first, in

7   terms of the across-carrier extrapolation, so for those carrier

8   J-Code quarter combinations where I have the array, if one

9   looks there, the ratio of difference to spending is about

10   29 percent. Okay, it's lower than for Medicaid because of this

11   thing we were talking about that went -- the median doesn't

12   move as much as the AWP moves. So about 29 percent.

13   For those carriers to which I'm extrapolating, it's

14   less than half that amount, so it's like 14 percent because I'm

15   accounting -- I'm sort of scaling down by even more than our

16   discussion a little while ago suggested to account for this

17   difference in the data.

18   THE COURT: So if you have, guesstimate here, a

19   hundred carriers here?

20   THE WITNESS: Ninety, I think there are.

21   THE COURT: Ninety, all right, ninety. If you had

22   eighty carriers, you'd be able to see a pattern and

23   extrapolate. But what if you only had five carrier arrays?

24   Did you just sort of say, "I can't do that"? Am I understanding

25   this wrong?

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1   THE WITNESS: No, no, you're understanding it

2   correctly. So I am essentially in this case aggregating

3   information from multiple arrays for the same carrier. So the

4   carriers definitely change. So Wisconsin Physician moved from

5   having five products to seven products, added in new products,

6   so they're changing all the time. So just as with Medicaid,

7   the notion that it's 10 states only, that's not the way that I

8   would phrase it because these arrays are constantly -- are

9   being updated quite a lot over the time period. So the

10   information that is included in the arrays, there's a lot of --

11   there are many, many arrays. I don't have the number off the

12   top of my head here, but there are dozens and dozens of arrays

13   that I'm using to calculate this difference-to-spending ratio.

14   And, you know, like I said, there's big variation within a

15   carrier. And then I'm using the information for those arrays

16   to extrapolate to this other group, which I recognize is, you

17   know, having drilled down on it, they are somewhat different.

18   And so this is, it's a harder -- I'll concede it's a harder

19   exercise just because of the specifics of it. We're talking

20   about arrays and so forth. But the carriers were all operating

21   under sort of similar guidelines; and to the extent that they

22   do differ somewhat, I'm really penalizing, I'm really cutting

23   down that difference-to-spending ratio, whereas with

24   Medicaid --

25   THE COURT: Is there any evidence that CMS actually

1   went and surveyed and regulated the carriers? You say they're

2   all under the CMS, and my impression from other litigation --

3   I've been doing this now for a decade -- is that CMS actually

4   didn't do very much to survey the carriers, right? I mean,

5   they may have kept track of the data, but they weren't policing

6   them. Is that wrong? Do we have evidence to the contrary?

7   THE WITNESS: That's probably not my best --

8   THE COURT: All right. But I'm just saying, you keep

9   saying they were supervised by the same group. They were like

10 lone wolves, weren't they, each one doing their own thing?

11   THE WITNESS: Well, I think that there's some sense in

12 which carriers look to one another to some extent.

13   THE COURT: Well, do you have evidence of that?

14   THE WITNESS: There are some cases where certain

15 carriers that I analyzed eventually piggybacked on Wisconsin

16 Physician Services, for example, so there is some evidence of

17 this. But I will concede, there's no question, this was a

18 harder exercise. And because of the -- I mean, I tried through

19 a number of channels to be very conservative here; drop six

20 products from the analysis, don't go back in time all the way

21 to 1991 because there's not enough Abbott products, you know,

22 really scale down the difference going from my sample to the

23 other group because it's clear that the Abbott AWP is being

24 used less frequently there. And this, in my professional

25 judgment, using all of my experience as an economist -- and,

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1   you know, I will admit this is a hard -- this is not --

2   THE COURT: This is a harder nut.

3   THE WITNESS: This is a harder nut to crack.

4   THE COURT: So if I were concerned about the whole

5   thing you did, would at least the one quarter that are Abbott

6   that are right at the median, would that be a subset that you

7   felt confident with?

8   THE WITNESS: Absolutely, I mean, I think that at some

9   level it seems plausible -- so I think it's 1.3 million

10 claims in this other group of carriers that have an Abbott AWP

11 as the allowed amount. And I'm sure that one can find an

12 example where in one of those NDC quarter combinations, both

13 Abbott and Baxter had 10.03, like, there's a little bit of

14 that, but it's certainly not the dominant thing going on,

15 having looked myself at these arrays. But, absolutely, those

16 are -- it is clear what's going on.

17   THE COURT: So for the one quarter where Abbott's was

18 right at the J-Code, you would say it was an extremely accurate

19 methodology, I think. With the others, you're saying you're

20 doing the best you can, the most conservative you can with the

21 data you have?

22   THE WITNESS: Absolutely. And it is my professional

23 judgment that if I had perfect array data for all eleven

24 products for all of these carriers over this entire period, the

25 difference that would emerge from that analysis with perfect

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1   data would be considerably higher than the one that is

2   resulting here.

3   THE COURT: You mean more adverse to Abbott?

4   THE WITNESS: More adverse to Abbott, that's right.

5   I'm sure there are cases where maybe if we pulled out data for

6   North Carolina Blue Shield and we just happened to have their

7   array, in the same way that some states are a little above the

8   extrapolation, some states are below, sure, that would be true.

9   But in general, the combination of dropping six J-Codes from

10   the analysis, dropping big chunks of the time period from the

11   analysis, scaling down when going from the sample to the other

12   group -- and this is, you know, really, I mean, this was a

13   hard -- this was something that I kind of warmed up on. This

14   is a hard part of the analysis, but it is, in my judgment, this

15   number, if I had perfect data, that difference would be

16   considerably larger.

17   Q.   Dr. Duggan, what are all the dashes on Tables 43 and 44?

18   I'm not sure that's been clearly described.

19   A.   The dashes on 43 and 44 represent those carrier time

20   period combinations that I just drop. So, for example, for

21   Connecticut General on that third line, you can see that I'm

22   only going back in time to the first 130,000 claims. I ignore

23   the preceding 190,000 claims because, as I mention in the

24   report, the frequency with which they're using the Abbott AWPs

25   in that earlier period is much lower. So I'm zeroing out

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1   there, I'm zeroing out at many other periods within carriers,

2   so in a sense penalizing more -- it's a little bit analogous to

3   the sort of Medicaid accounting for the fact that the spreads

4   were narrower at the beginning of the period, but I'm

5   penalizing more aggressively with this Medicare analysis than

6   there.

7   THE COURT: Thank you. Now, are you almost done

8   because I'd like to finish him today, and then we'll go

9   tomorrow?

10   MR. LAVINE: Yes, very close to done, Judge.

11   THE COURT: So three minutes, done.

12 Q.   Did you test your Medicare methodology and extrapolation?

13 A.   I mean, this one is a harder one to -- it's a more

14 difficult one to test, admittedly, because I don't have the

15 North Dakota Blue Shield, I don't have those arrays, and there

16 would be more variability for this case than the others.

17   THE COURT: Have you tried to get those, the arrays?

18   THE WITNESS: Basically my understanding is that all

19 of the arrays that could be obtained were obtained, and that,

20 you know, I guess in the same way one could think, you know,

21 maybe it's a draw-the-line kind of thing, so I didn't go to

22 some of those other products and so forth, but my understanding

23 is that the arrays that could be obtained, given the -- I mean,

24 this was an enormous amount of work to assemble these arrays

25 for all these products -- is that I got what was available.

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1   But I do sort of use the methodology within these carriers to

2   try to see, you know, if I pretend the data starts somewhat

3   later and so forth, do I get similar results? And the results

4   in the aggregate are similar, you know, I'll concede that it's

5   not as -- it would be -- it's a -- but, yes, I did probe it to

6   the extent that the available data permitted.

7   And I should note, the data that are available, this

8   is an incredible amount of data, claim-by-claim data for all

9   22 million claims during this eleven-year time period of

10   interest, and, you know, to having drilled down to this data to

11   a great extent to try to come up with the most accurate

12   estimate as possible, and where it looked like this

13   extrapolation was not appropriate across products, earlier

14   periods and so forth, I just didn't do it. I just zeroed it

15   out.

16   THE COURT: Thank you.

17   Q.   So on average, did you examine the difference between the

18   allowed amounts in the Medicare claims where you matched them

19   to arrays as compared to where you did not match them?

20   A.   Yes, and in general the two were similar. You know, they

21   weren't identical, but they were qualitatively similar. It's

22   not like the remaining carriers were reimbursing at 350 while

23   the carriers for which I had data were reimbursing at 10. You

24   know, there were some -- it was comparable to somewhat -- I

25   think the allowed amounts were somewhat lower for the remaining

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1   carriers, but pretty close. And to the extent that they were

2   lower, that would lead to a lower difference as well, given my

3   methodology.

4   Q.   But that issue, that was something you considered?

5   Q.   Absolutely, absolutely.

6   THE COURT: Are you finished?

7   MR. LAVINE: One wrap-up question?

8   THE COURT: Absolutely.

9   Q.   Can you describe and explain your level of confidence that

10 the work that you performed in this case and the opinions you

11 reached are to a reasonable degree of economic certainty.

12 What's the level of your confidence?

13 A.   I, you know, having worked incredibly hard in deploying,

14 like, all the skills that I've acquired over graduate school

15 and my ten years as a professor, it is my judgment that the

16 estimates that I've come up with are incredibly reliable, are

17 very, very reliable. And I feel, you know, that to the extent

18 that the available data permitted or the available time

19 permitted, I probed the validity of these analyses; you know,

20 the within-state extrapolation, the across-state extrapolation,

21 the within-carrier extrapolation. I'll concede the

22 across-carrier extrapolation is a little tougher, but, still, I

23 feel very confident that were perfect data assembled with

24 infinite time, that the difference, that the aggregate

25 difference would be higher. But, you know, I've tried to

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1   telescope in on the most accurate estimate possible, and, when

2   there were forks in the road, taken a conservative approach.

3   So I feel really very good about the precision of this. I

4   would have liked the 6 percent to be 0 percent, but other than

5   that, I feel pretty good.

6   THE COURT: Thank you. So we all need a break here.

7   Tomorrow, now, what time is the Schering-Plough?

8   THE CLERK: Three.

9   THE COURT: Three o'clock, so I don't think that's

10   going to take that long, but I may be wrong. So we're going to

11   go from 2:00 to 3:00. We'll take a break for a possible

12   settlement. And I think, Department of Justice, are any of you

13   involved in that?

14   MR. HENDERSON: The Department of Justice will be here

15   for the settlement hearing.

16   THE COURT: How long will that take? Are there

17   objections?

18   MR. HENDERSON: Not that I know of, but I don't know.

19   THE COURT: If there are no objections, it will be

20   very fast. If there are objections, it could be, let's say,

21   half an hour, but otherwise you have the rest of the afternoon.

22   If we don't finish, it's very important and very difficult --

23   we'll finish at least you tomorrow so you can leave. And your

24   experts, do you want to have -- I know it's very expensive --

25   do you want them here no matter what?

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1   MR. DALY: Your Honor, if we're going just 2:00 to

2   5:00 with an indeterminate break in there, I'm thinking I may

3   want to release them.

4   THE COURT: What?

5   MR. DALY: I may want to release them for tomorrow on

6   the ground that I think, if we have essentially two hours

7   tomorrow, I think it will take me two hours to --

8   THE COURT: I'm thinking it's very important.

9   MR. DALY: Yes.

10   THE COURT: And I don't know how you thought we were

11   going to squeeze in spoliation and the motion for summary

12   judgment. Either you're the most optimistic people in America

13   or I should be complimented that you thought I understood this

14   already. This has been unbelievably helpful today, and I thank

15   you. I'm sure tomorrow I'll learn more, but maybe if you

16   wanted to keep one expert around, there should be some time for

17   it. I think the Department of Justice should know, right,

18   whether or not there are going to be objections from New York

19   and Massachusetts? At this point you should know.

20   MR. HENDERSON: I think we should. The last

21   communication I heard, your Honor, there was still a little

22   uncertainty about it. We didn't have a final communication

23   from the states. I'm a little on the sidelines, so I don't

24   know the details, but we think there are no objections.

25   THE COURT: Well, could you e-mail Mr. Alba and let us

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1   know and let them know because, truthfully, if you have two

2   hours, then there will be some re -- I mean, I think, as a

3   practical matter, at most we'd hit one expert, even without --

4   even if I had only --

5   MR. DALY: I think at most, Judge, I agree.

6   THE COURT: If you want to let them go because of the

7   expense, I'd certainly understand that --

8   MR. BREEN: Your Honor, I think it's very unlikely

9   there are going to be any objections.

10   THE COURT: The reason I need to do this is, there are

11   reasons I have to approve this by year end, or I wouldn't have

12   interrupted you. It has something to do with, what is it, a

13   corporate transaction?

14   MR. BREEN: Acquisition.

15   THE COURT: Yes, an acquisition. So you can find out

16   the nitty-gritty details from them, but if there are no

17   objections, this will not take more than three minutes. If

18   there are objections, I need to finish it, which is the only

19   reason I'm cutting into your valuable time.

20   MR. DALY: We'll work with the Court's schedule.

21   THE COURT: All right, thank you.

22   MR. DALY: Thank you, Judge.

23   THE CLERK: Court is in recess.

24   (Adjourned, 5:03 p.m.)

25

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1   C E R T I F I C A T E

2

3

   UNITED STATES DISTRICT COURT)
4 DISTRICT OF MASSACHUSETTS   ) ss.
   CITY OF BOSTON   )

5

6

7   I, Lee A. Marzilli, Official Federal Court Reporter,

8 do hereby certify that the foregoing transcript, Pages 1

9 through 99 inclusive, was recorded by me stenographically at

10 the time and place aforesaid in Civil Action No. 01-12257-PBS,

11 In Re: Pharmaceutical Industry Average Wholesale Price

12 Litigation, and thereafter by me reduced to typewriting and is

13 a true and accurate record of the proceedings.

14   In witness whereof I have hereunto set my hand this

15 7th day of January, 2010.

16

17

18

19

20   /s/ Lee A. Marzilli
             _____
21   LEE A. MARZILLI, CRR
             OFFICIAL FEDERAL COURT REPORTER
22

23

24

25